UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

December 18, 2002

OFFICE OF THE ADMINISTRATOR EPA SCIENCE ADVISORY BOARD

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The attached draft report is a draft report of the EPA Science Advisory Board (SAB). The draft is still undergoing final internal SAB review, however, in its present form, it represents the consensus position of the panel involved in the review. Once approved as final, the report will be transmitted to the EPA Administrator and will become available to the interested public as a final report.

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- 1. Has the Committee adequately responded to the questions posed in the Charge?
- 2. Are any statements or responses made in the draft unclear?
- 3. Are there any technical errors?

For further information or to respond to the questions above, please contact:

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49 50 51 **United States** EPA-SAB-RAC-03-0XX **EPA Science Advisory Environmental** Board (1400A) December 2002 **Protection Agency Washington DC** www.epa.gov/sab 52 **ŞEPA MULTI-AGENCY** RADIOLOGICAL 54 LABORATORY 55 **ANALYTICAL** 56 PROTOCOLS (MARLAP) 57 **MANUAL: AN SAB** 58 **REVIEW** 59 60 61 62 63 REVIEW OF THE MARLAP 64 MANUAL AND APPENDICES 65 BY THE MARLAP REVIEW 66 PANEL OF THE RADIATION 67 **ADVISORY COMMITTEE** 68 69 **WORKING DRAFT DECEMBER 18, 2002** 70 DO NOT CITE OR QUOTE 71 72 73 75 78

79 Draft dated December 18, 2002 80 81 EPA-SAB-RAC-03-0XX 82 83 The Honorable Christine Todd Whitman 84 Administrator 85 U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW 86 87 Ariel Rios Building, Mail Code 1100 88 Washington, DC 20460 89 90 Dear Governor Whitman: 91 92 Subject: An SAB Review of the Multi-Agency Radiological Laboratory Analytical 93 Protocols (MARLAP) Manual 94 95 The Office of Radiation and Indoor Air (ORIA) requested that the Radiation Advisory Committee (RAC) establish a panel to review the Multi-Agency Radiological Laboratory 96 97 Analytical Protocols (MARLAP) Manual. The MARLAP Manual represents the first inter-98 agency technical document intended to provide consistent guidance for laboratories and users of 99 laboratory services in planning, implementation, and assessment of projects entailing radiological 100 data and protocols. It is intended to complement the Multi-Agency Radiation Survey and Site 101 Investigation Manual (MARSSIM) developed through a similar process during the 1990s. 102 103 The MARLAP Manual is the result of over seven years of planning, research, and 104 documentation, and was developed in partnership by seven federal agencies, departments, and 105 commissions: the U.S. Environmental Protection Agency (EPA), the Department of Energy 106 (DOE), the Department of Defense (DoD), the Nuclear Regulatory Commission (NRC), the 107 National Institute of Standards and Technology (NIST), the U.S. Geological Survey (USGS), and 108 the U.S. Food and Drug Administration (FDA). In addition, State participation in the 109 development of the Manual involved contributions from representatives from the State of 110 California and the Commonwealth of Kentucky. For the purpose of the RAC review, this group 111 is termed the federal "MARLAP Work Group." 112 113 The MARLAP Review Panel of the Science Advisory Board's Radiation Advisory 114 Committee convened on April 8 (conference call), April 23-25, June 27 (conference call), and 115 September 24-26, 2002 in Washington, DC to review the MARLAP Manual. In addition, the parent committee to the MARLAP Review Panel – the Radiation Advisory Committee (RAC) – 116 117 met in earlier, publicly advertised meetings, to plan for the MARLAP review. In particular, 118 MARLAP was introduced to the RAC at its August 1, 2000 meeting in Washington, DC. This 119 was followed by a planning session at the RAC's December 13, 2000 meeting.

The Panel wishes to bring to your attention the partnership that produced this Manual, which was led by Dr. John Griggs of ORIA and involved technical staff from different government entities working together, represents the very best in government practices. Such collaboration brings collective wisdom, together with the practical application of consistent and comprehensive science methodologies, into harmony with a variety of regulatory and compliance practices. We believe that this effort deserves special mention for the common sense approach it brings to the implementation of government programs and guidelines.

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Through the auspices of ORIA, the federal MARLAP Work Group posed three charge questions to the Panel regarding:

- (1) the effectiveness and clarity of the overall approach,
- (2) the technical accuracy of the guidance on laboratory operations, and
- (3) the technical accuracy and clarity of the guidance on measurement statistics.

The MARLAP Review Panel added a fourth charge question during a planning conference call pertaining to:

(4) the overall integration and implementation issues.

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The MARLAP Review Panel found the Manual to be well conceived and expects that it will be a valuable reference, particularly helpful to analytical laboratories and users of laboratory services working with radioanalytical data and protocols. The primary recommendations from the Panel involve reorganization of the Manual to make it user friendly and facilitate its intended use. The comments and recommendations offered by the Panel should be construed as constructive criticism as they are intended solely to assist in improving a document that is already very comprehensive and thorough.

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With regard to Charge Question #1 (relating to the effectiveness and clarity of the overall approach), the Panel finds that the performance-based, flexible approach in MARLAP is appropriate and, for the most part, presented clearly and logically in the draft MARLAP Manual. The Panel finds the guidance provided with regard to a graded approach for projects of different size and scope, as well as the emphasis on data quality, adequate and reasonable for the decision being supported. The linkage of the planning, implementation, and assessment phases of projects involving radioanalytical data is effective. However, the Manual is consequently massive, and finding the information needed for a specific radioanalytical project is difficult at this stage, especially for a novice or infrequent user. In its attempt to make the various chapters stand alone, the MARLAP Work Group may have introduced excessive redundancy. Moreover, some of the guidelines proposed to the laboratories appear to be insufficient or vague. The Panel recognizes that a lack of consensus between different members of the MARLAP Work Group may be inevitable, due to the multi-agency input to this document and the different governing regulatory requirements under which those agencies must operate. Nonetheless, the Panel recommends that a well-defined "consensus" solution be adopted in making recommendations to the users. In addressing these and other questions, the Panel proposes several specific suggestions for reorganizing and editing the document and improving its overall usefulness and accessibility.

With regard to Charge Question #2 (relating to the technical accuracy of the guidance), the Panel finds that the document is an impressive compilation of information and recommendations that should be immensely useful to radiochemical analysis practitioners. It also finds the guidance to be, on the whole, reliable and well thought out; however, as would be expected with such a large compendium of information, some technical inaccuracies and inconsistencies are identified. The Panel includes the most important of these issues in the text of its Review Report and recommends some changes or additions to several of the chapters. It also suggests some changes in the organizational structure of the Manual to add clarity and usefulness. The bulk of the Panel's specific concerns are addressed in an appendix to its report.

With regard to Charge Question #3 (involving the guidance on measurement statistics), the Panel finds that statistical issues are addressed very well in the MARLAP Manual but offers several suggestions for reorganization and clarification to enhance its value, specifically for laboratory directors and staff. In particular, both the terminology used in the MARLAP Manual as well as the treatment of uncertainty propagation in measured values require some reevaluation, and possible revision.

In terms of Charge Question #4 (related to self-initiated Panel questions on the issue of overall integration and implementation), the Panel suggests that in addition to the integration with the earlier MARSSIM (2000) document, it might be useful to devote a short section at the beginning of the Manual to show how the performance-based approach is suitable for decisions regarding the cleanup of radioactively contaminated sites. Although the Panel recognizes that MARLAP is not limited to site cleanup decisions, these represent some of the most important drivers for the creation of MARLAP. The proposed new section would also help elucidate the areas of overlap between MARLAP and MARSSIM, as well as emphasize their differences in scope and coverage.

Finally, the Panel offers some suggestions beyond the charge given by the federal MARLAP Work Group, regarding implementation of the Manual's recommended protocols after its completion and release:

(1) Due to the complexity of the issues addressed in MARLAP, the Panel recommends that EPA undertake a program to train laboratory personnel and users of radio-analytical data in much the same manner as occurred for the MARSSIM activity.

 (2) The Panel also recommends that the agencies, departments, and commissions involved in the development of MARLAP support a professional education program to generate a new generation of experts in radioanalytical techniques, to offset the trend towards a diminishing pool of available experts.

(3) The MARLAP document should be maintained as a "living document" and involve an iterative process whereby user suggestions can be incorporated into future revisions.

(4) The success of this and a previous multi-agency effort (i.e., MARLAP and MARSSIM) in addressing complex multidisciplinary environmental issues leads us to recommend that multi-agency approaches be extended to other EPA activities.

The Panel also wishes to express to you that one of its main concerns with the draft MARLAP does not involve its technical content but rather the ease and practicality of its use as a tool. User implementation of its recommendations to use a performance-based approach may be frustrated by the fact that the selection of specific radiochemical protocols is often driven by the requirements of existing methods set as standards by different organizations. Until these methods are revised, and commitments from EPA and other authoring organizations are obtained, the radiochemistry community may be in conflict over the application of MARLAP guidance. The Panel therefore encourages you to initiate a review of your agency's existing regulations and guidance on radioanalytical protocols and to revise those documents as appropriate to reflect the MARLAP performance-based approach.

We appreciate the diligence and cooperative spirit in which this ambitious project has been undertaken and congratulate its participants. On behalf of members of the RAC and the MARLAP Review Panel, we wish to thank you for your consideration and look forward to your response.

222 Sincerely, 223

Dr. William H. Glaze, Chair
EPA Science Advisory Board
Executive Committee

Dr. Janet A. Johnson, Chair Radiation Advisory Committee and MARLAP Review Panel EPA Science Advisory Board

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ABSTRACT The EPA Science Advisory Board's Radiation Advisory Committee and the MARLAP Review Panel (the Panel) reviewed technical aspects of the draft Multi-agency Radiological Laboratory Analytical Protocols (MARLAP) Manual dated August 2001. This document was developed collaboratively by seven federal agencies, departments, and commissions having authority for regulating radioactive materials, and two states. The Panel finds that MARLAP effectively addresses the need for a nationally consistent. performance-based approach for planning, implementing, and assessing radioanalytical measurements to address regulatory concerns. The Manual's graded approach encourages a user to select a set of analytical procedures, with associated precision and reliability, suited to the complexity and importance of the problem being addressed. It does a thorough job of explaining how decision makers should make choices in the selection of hypotheses that help determine the confidence levels associated with the results obtained from analytical laboratories. The Manual's guidance on laboratory operations is generally technically sound although highly variable in scope and level of detail provided. Guidance on measurement statistics is also technically sound but perhaps overly detailed. The Panel recommends reorganization and a thorough technical edit of the Manual to improve its flow, add clarity and logic, and reduce redundancy so as to make it easier to use. The Panel also stresses the need to include more explicit examples to better illustrate the application of each step in the performance-based approach to activities of differing size and complexity. The Panel recommends that the EPA undertake a training program for MARLAP users and that it use the classes as a mechanism for seeking input that can be incorporated into future revisions of the Manual. Word count: 268 (NOTE: NTIS recommends a max. word count of 250)

Key Words: Analytical Protocols, Protocol Assessment, Protocol Implementation,

Protocol Manual, Radiological Analytical Protocols

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1. EXECUTIVE SUMMARY

The MARLAP Manual is intended to provide consistent guidance for laboratories and users of laboratory services, for the planning, implementation, and assessment of projects entailing radioanalytical data and protocols. The MARLAP Manual was developed in partnership by seven federal agencies, departments, and commissions: the U.S. Environmental Protection Agency (EPA), Department of Energy (DOE), Department of Defense (DoD), Nuclear Regulatory Commission (NRC), National Institute of Standards and Technology (NIST), U.S. Geological Survey (USGS), and U.S. Food and Drug Administration (FDA). State participation in the development of the Manual involved contributions from representatives from the State of California and the Commonwealth of Kentucky. For the purpose of the Radiation Advisory Committee (RAC) review, this group is termed the federal "MARLAP Work Group."

The RAC finds that the development of the MARLAP Manual is an excellent example of interagency cooperation in line with a similar effort that produced the Multi-agency Radiation Survey and Site Investigation Manual (MARSSIM). Use of an interagency partnership to produce the MARLAP Manual represents the very best in government practices by involving technical staff from different government entities working together. Such collaboration brings collective wisdom and practical application of consistent and comprehensive science methodologies into harmony with a variety of regulatory and compliance practices. The RAC believes that this effort deserves special mention for the common sense approach it brings to the implementation of government programs and guidelines. The multi-agency authorship of MARLAP and the apparent consensus on a single overall "performance-based" approach gives the reader confidence in the reliability of the guidance and the logical foundation that underlies it.

Through the auspices of EPA's Office of Radiation and Indoor Air (ORIA), the federal MARLAP Work Group posed three charge questions to the RAC regarding: 1) the effectiveness and clarity of the overall approach; 2) the technical accuracy of the guidance on laboratory operations; and 3) the technical accuracy and clarity of the guidance on measurement statistics. To respond to the charge, the RAC established the MARLAP Review Panel ("the Panel") as a RAC subcommittee, augmented by consultants. Following a planning conference call, the Panel added a fourth charge question pertaining to overall integration and implementation issues.

With regard to Charge Question #1 (relating to the effectiveness and clarity of the overall approach), the Panel finds that the performance-based and flexible approach in MARLAP is appropriate and, for the most part, presented clearly and logically in the draft MARLAP Manual. The Panel finds the guidance to be reasonable with regard to application of a graded approach for projects of different size, scope, and complexity, as well as the emphasis on data quality sufficient for the decision being supported. The linkage of the planning, implementation, and assessment phases of projects involving radioanalytical data is effective. However, the draft Manual is consequently massive, and finding the information needed for a specific radioanalytical project may be difficult, especially for a novice or infrequent user. In its attempt to make each chapter relatively self-contained, the federal MARLAP Work Group may have introduced excessive redundancy. Moreover, some of the guidelines proposed to the laboratories are insufficient or vague. Although the Panel recognizes that a lack of consensus among members of the federal MARLAP Work Group may be inevitable due to the different governing regulatory requirements

for each of the participating agencies, the Panel recommends that a well-defined "consensus" solution be adopted in making recommendations to the users. To address these and other concerns, the Panel proposes several specific suggestions for reorganizing and editing the document to improve its overall usefulness and accessibility.

The Panel also recommends the inclusion of more examples to illustrate the planning process and the graded approach, so as to bring these to life for the reader. A variety of clearly presented and realistic scenarios will be critical to the success of MARLAP and should emphasize the potential benefits of planning and using a graded approach. The Panel recognizes that policies are often implied in the assumptions that are adopted as part of the planning process, and that it is difficult for a multi-agency document to address this nontechnical aspect. The Panel also recognizes the concern of the federal MARLAP Work Group that case studies or scenarios in the Manual could be interpreted by some users as setting or endorsing a precedent. Nonetheless, the Panel recommends that this concern be addressed upfront. Furthermore, to address the concern that regulatory agencies may try to apply the entire MARLAP process to situations and organizations for which a full-scale effort would not be appropriate, the Panel suggests the inclusion of more explicit guidance, including examples, on how to scale back the process to a level appropriate to the decision under consideration.

In reference to Charge Question #2 (relating to the technical accuracy of the guidance), the Panel finds that the draft Manual is an impressive compilation of information and recommendations that should be immensely useful to radiochemical analysis practitioners. The Panel also finds the guidance to be, on the whole, reliable and well thought out; however, as would be expected with such a large compendium of information, numerous technical inaccuracies and inconsistencies are identified. The Panel includes the most important of these issues in the text of its Review Report and recommends some changes or additions to the discussions in specific chapters. The Panel also suggests some changes in organizational structure so as to streamline and add clarity to the discussions, improve the logic of its flow, and in general increase its usefulness as a reference. The bulk of the Panel's specific concerns are addressed in an appendix to the Panel's report (See Appendix C and D).

With regard to Charge Question #3 (involving the guidance on measurement statistics), the Panel finds that statistical issues are addressed very well in the MARLAP Manual but offers several suggestions for reorganization and clarification to enhance its value, specifically for laboratory directors and staff. In particular, the terminology used in the draft MARLAP Manual and the treatment of uncertainty propagation in measured values require some re-evaluation and, perhaps, revision.

In terms of Charge Question #4 (related to the self-initiated Panel question on the issue of overall integration and implementation), the Panel suggests that in addition to better integration with the earlier MARSSIM (2000) document, it might be useful to devote a short section at the beginning of the Manual to show how the performance-based approach is suitable for decisions regarding the cleanup of radioactively contaminated sites. Although the Panel recognizes that MARLAP is not limited to site cleanup decisions, these represent some of the most important drivers for the creation of this Manual. The proposed new section would also help elucidate the areas of overlap between MARLAP and MARSSIM, as well as emphasize their differences in

scope, coverage, and guidance.

In general, the Panel emphasizes that its comments and recommendations are intended to facilitate the use, and enhance the user-friendly construct, of an already superior product. The comments and recommendations offered by the Panel should be construed as constructive criticism intended solely to assist in improving a document that is already very comprehensive and thorough. Some of the main concerns with the draft MARLAP do not involve the technical content but rather the ease and practicality of its use as a tool. User implementation of its recommendations to use a performance-based approach may be frustrated by the fact that the selection of specific radiochemical protocols is often driven by the requirements of existing methods set as standards by different organizations. Until these methods are revised, and commitments from the authoring organizations are obtained, the radiochemistry community may be in conflict over some applications of MARLAP guidance.

The Panel emphasizes the need for a thorough technical edit, the main objectives of which should be to: 1) remove the considerable amount of redundancy, 2) ensure internal consistency among the chapters in presentation style and formatting, 3) make wider and more consistent use of effective techniques for presenting information, and 4) verify and proof read all references, web-site addresses, equations, tables, figures, and examples. To aid in this effort, the Panel notes several presentation and formatting techniques in the draft Manual that it found to be particularly effective in emphasizing important points.

Finally, the Panel offers some suggestions beyond the charge given by the federal MARLAP Work Group regarding implementation of the Manual after its release:

1. Due to the complexity of the issues addressed in MARLAP, the Panel recommends that EPA undertake a program to train laboratory personnel and users of radioanalytical data in much the same manner as occurred for the MARSSIM activity.

2. The Panel also recommends that the agencies, departments, and commissions involved in developing MARLAP support a professional education program to generate a new generation of experts in radioanalytical techniques, to offset the trend towards a diminishing pool of available specialists.

3. The MARLAP document should be maintained as a "living document" and involve an

iterative process whereby user suggestions can be incorporated into future revisions.

4. The success of MARLAP and MARSSIM in addressing complex multidisciplinary environmental issues leads the Panel to recommend that multi-agency approaches be extended to other EPA activities.

2. INTRODUCTION AND CHARGE

The EPA's Office of Radiation and Indoor Air (ORIA) requested that the Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) review the Multi-Agency Radiological Laboratory Protocols Manual (MARLAP). The RAC review was initiated in August 2000 while the MARLAP was still under development, at which time the RAC initiated action to establish a MARLAP Review Panel comprised of RAC members and consultants. The draft Manual was made available to the Review Panel in September 2001. The Panel's review was completed in September 2002 and its report was adopted and approved by the RAC in November 2002 and transmitted in December 2002 for an Executive Committee Review. Appendix A describes the details of the RAC review schedule and process. Appendix B defines the acronyms and abbreviations used in this report.

2.1 Background About the MARLAP Manual

The MARLAP Manual provides "guidance for the planning, implementation, and assessment of projects that require the laboratory analysis of radionuclides." The intent of the Manual is to "provide the guidance necessary for national consistency in the form of a performance-based approach for meeting a project's data requirements" and to help "ensure the generation of radioanalytical data of known quality, appropriate for its intended use." The MARLAP is not intended to be a "cookbook;" the Manual contains guidance but not specific laboratory procedures.

The MARLAP Work Group that developed the Manual consists of representatives of the Environmental Protection Agency (EPA), Department of Defense (DoD), Department of Energy (DOE), Nuclear Regulatory Commission (NRC), National Institute of Standards and Technology (NIST), U.S. Geological Survey (USGS), U.S. Food and Drug Administration (FDA), the Commonwealth of Kentucky, and the State of California.

2.2 Charge Questions

The specific charge questions posed to the RAC by the MARLAP Work Group through the auspices of ORIA were as follows:

- Charge Question 1: Is the overall approach present in Part 1 of MARLAP for the planning, implementation and assessment phases of projects which require analysis for radionuclides technically acceptable?
- 18 Ia. Is the performance-based approach presented clearly and logically?
- 19 1b. Is the approach reasonable in terms of ease of implementation?
- *Ic.* Does the approach effectively link the three phases (planning, implementation, assessment) of a project?

Charge Question 2: Is the guidance on laboratory operations in the Part II chapters technically accurate? Does it provide a useful resource base of information for a laboratory's implementation of a performance-based approach?

Charge Question 3: Is the guidance on measurement statistics - specifically measurement uncertainty and detection and quantification capability - technically accurate, clearly presented, and useful for implementation by appropriately trained personnel?

2.3 RAC Review Process

The MARLAP was introduced to the RAC at its August 1, 2000 meeting in Washington, DC and conducted a planning meeting on MARLAP and other topics on December 12-14, 2000.. The RAC determined that additional expertise would be needed for the review. Consequently, several consultants were added to the MARLAP Review Panel to assist in addressing the organizational aspects of the Manual as well as the accuracy of its radiochemical and statistical guidance.

The sequence and scope of the Review Panel's conference calls and meetings, and its interactions with the MARLAP Work Group (who were responsible for the Manual's content), are described in Appendix A. Two aspects of the review process are particularly worthy of the reader's attention. First, during its April 23-25, 2002 public meeting, the Panel subcommittee responding to Charge Question #1 (relating to the effectiveness and clarity of the overall approach) employed a tool that is unique to this review, at least for the RAC. In order to get a sense of how a laboratory manager or other critical users might perceive MARLAP, the Subcommittee engaged in a role-playing exercise with members of the MARLAP Work Group. This exercise was very enlightening, particularly in identifying and clarifying areas where MARLAP may be confusing and/or not a practical guide for the user. The exercise subsequently served as the basis for one of the Panel's recommendations on MARLAP training techniques.

Secondly, although not unusual among RAC reviews of EPA products, the cooperative process between the Panel and the federal MARLAP Work Group proved to be very useful. It facilitated the flow of information from the federal MARLAP Work Group to the Panel as well as providing an opportunity for the federal MARLAP Work Group to hear and understand the concerns of the Panel. Questions that might have been posed in the Panel's draft Review Report were addressed at the time they were raised, thus saving much effort and reducing the need for later corrections. The RAC very much appreciates the time and effort the federal MARLAP Work Group devoted to explaining aspects of the Manual and the rationale behind its organization. While the Panel worked in close cooperation with the federal MARLAP Work Group, that process did not compromise the independence of the peer review.

2.4 Report Organization

Responses to specific charge questions are contained in Sections 3, 4, and 5 of this report. In addition to responding to the specific charge questions, the Panel addressed several issues that went beyond the charge. These issues are presented in Section 6. Section 7 summarizes the Panel's most important findings and recommendations. Appendix C to this report compiles the Panel's comments on technical aspects of the Manual, relating to the accuracy, completeness, and clarity of MARLAP's technical discussions. Appendix D lists the Panel's editorial comments that address the need for more precise or succinct wording, additional detail in the guidance, corrected references, cross-referencing, and clarification of statements or terminology used in the Manual.

Names of subcommittee chairs and members, and a list of the MARLAP Manual chapters and appendices assigned to each Panel subcommittee, are included in Appendix A of this report.

3. RESPONSE TO CHARGE QUESTION #1: TECHNICAL ACCEPTABILITY, PRESENTATION, AND EASE OF IMPLEMENTING THE PLANNING, IMPLEMENTATION AND ASSESSMENT PHASES

<u>Charge Question #1</u>: Is the overall approach presented in Part 1 of MARLAP for the planning, implementation and assessment phases of projects which require analysis for radionuclides technically acceptable?

- *la.* Is the performance-based approach presented clearly and logically?
- 1b. Is the approach reasonable in terms of ease of implementation?
- 1c. Does the approach effectively link the three phases (planning, implementation, assessment) of a project?

3.1 Overall Response to Charge Question #1

Compiling and organizing information and guidance related to the acquisition and use of radioanalytical analyses is a formidable but worthy task to be undertaken by a multi-agency committee. The federal MARLAP Work Group is largely successful in achieving its goal of developing a consensus document on this complex topic. Overall, the MARLAP Manual is a very impressive document with almost encyclopedic amounts of useful information. Chapters 1 to 9 in Part I are well prepared and thoughtfully organized, making this document very useful for persons needing to obtain or provide radioanalytical services for large-scale projects. The Manual does a thorough job of explaining how decision makers should make choices in the selection of hypotheses that help determine the confidence levels associated with the results obtained from analytical laboratories. Finally, the multi-agency authorship of MARLAP and the apparent consensus on a single overall approach gives the reader confidence about the reliability of the guidance.

The Panel strongly supports the graded approach advocated for the implementation of MARLAP, in which resources applied to a problem are appropriate to the size and complexity of the project. The Panel also strongly endorses MARLAP guidance that the planning process be viewed as an iterative process, rather than linear or stepwise, to ensure that the final product precisely meets all the requirements associated with data needs and a decision-based approach. An iterative process also permits the incorporation of new information as it is received, allowing the planners flexibility to modify or change earlier decisions as required, so that the most resource-effective approach to the problem can be developed and implemented.

3.1.1 Response to Charge Question #1a

With only a few reservations about explaining the context in which MARLAP will operate, the performance-based and flexible approach is well designed and appropriate, and is presented clearly and logically in the draft document. The exposition is generally better than that typical of such large and complex draft technical documents at this stage of review.

3.1.2 Response to Charge Question #1b

Although some of the guidance in MARLAP may challenge the capabilities of those who must plan, manage, and conduct radiochemical analyses (see detailed discussion in Sections 3.2 and 3.3), the approach is reasonable, especially in light of the graded approach for projects of different scope and importance, and the emphasis on data of quality sufficient for the decision being supported rather than on specific requirements for analytical procedures or data precision and accuracy.

3.1.3 Response to Charge Question #1c.

The linkage of the planning, implementation, and assessment phases is largely effective as well. However, the Panel recommends that MARLAP provide guidance or recommendations to the end user who receives the analytical data that are generated through MARLAP, with regard to traceability, compilation and archiving of the data. For certain types of projects the assembled data may be useful in the future in the context of a different project. However, such data will be useful only to the extent that they are compiled and stored with sufficient information regarding sampling location, method, sampling time, analytical procedure, and quality assurance and control aspects. Inclusion of a statement regarding this issue could be very beneficial to project planners and managers.

3.2 Detailed Comments on Organization and Presentation of Part I

The following comments are offered in the hope of further improvement, not as a criticism of this important effort. The comments are classified into the following categories: organization, presentation style, and the need for a thorough technical edit.

3.2.1 Organization

The organization of the draft MARLAP document is complicated, and it is not obvious how the user should most effectively make use of this thick two-volume manual. The present draft is wordy, with information being scattered and repetitive. The goal of producing standalone chapters is ineffective in practice because this repetition is distracting to those who are reading more than one chapter at a time, with the result that the reader very quickly loses interest. The following suggestions are made to address these shortcomings:

- 1. The goal should be to make Part I a stand-alone volume, replacing the goal of stand-alone chapters. The Panel envisions Part I as including the information presented in Chapters 1 to 9 and Appendices A to E.
- 2. Chapters should be thinned down and focused. Information in the chapters should be limited to that which the majority of users are likely to need to know, with the reader being referred to an appendix or references for extended discussions of exceptions, alternative options, or less common aspects.

- 3. In order to improve usability and reduce repetition, the Panel suggests that Appendix B should be incorporated in its entirety into Chapter 2. As it now stands, neither Appendix B nor Chapter 2 give the total picture, and the different numbering of steps in these two parts of the Manual adds to the confusion. If for some pressing reason the two cannot be merged, then at a minimum cross-references to appropriate sections of Appendix B should be sprinkled throughout Chapter 2 in order to tie the two together. Attachment B-1 to Appendix B also provides information that is important for understanding the underpinnings of a performance-based laboratory process; it may not need to be elevated to chapter status, but technically oriented readers should be encouraged to read it.
 - 4. Instead of discussing all planning process options, the main body of the Manual should stick with one model (Data Quality Objectives) and discuss the alternatives only in an appendix.
 - 5. Problems associated with navigating efficiently through the document could be minimized through the use of a decision tree to guide the user to sections that are relevant to a particular issue.
- 780 6. In the future, navigation through the document could also be made easier through the use of hyperlinks in a computerized version of MARLAP.
 - 7. In general, the document eventually answers almost every question that occurs to the reader while reading it. However, it is so extensive that questions that arise in one section may be answered only in another section well removed from it. Although the document has extensive cross-referencing, it could do even better in that regard. Examples are provided in the specific comments compiled in Appendices C and D.
- 787 8. The utility of the Manual would benefit from the inclusion of an index similar in design, use of key words, and level of detail to the one in MARSSIM (2000).

3.2.2 Presentation Style

During one of the Panel's subcommittee sessions, a member of the federal MARLAP Work Group observed that the emphasis of key points and redundancy were already built into the document, but that key points were nonetheless still being overlooked by new readers. Why is that the case? In its role as new readers, the Panel feels that the presentation style is often ineffective, and that it takes too long for the reader to "catch on" and to "see the big picture." The following suggestions are made to address that problem.

1. A well-written Executive Summary or Roadmap [such as the one in MARSSIM (2000)] could provide a means to unify MARLAP by using clear, simple text and figures to show the linkages among the chapters without the distracting repetition that is currently present. This summary of the major components of the MARLAP Manual should use figures and tables in the place of extensive text, as appropriate, to summarize sequential steps and/or interrelationships.

- 2. Acronyms are likely to be a major stumbling block at first for most readers. Although training and time may make some readers more comfortable with use of acronyms, the document is acronym-heavy and plain language should be used more often. Numerous acronyms appear to be good candidates for being dropped from the Manual and replaced with their full terms, such as ADC (analog to digital converter), AL (action level), ASL (analytical service laboratory), ATD (alpha track detector), BOA (basic ordering agreement), CC (charcoal canister), CL (central line of a control chart), COC (chain of custody), COR (contracting officer's representative), DL (discrimination limit), EDD (electronic data deliverable), GUM [Guide to the Expression of Uncertainty in Measurement (ISO, 1995)], and NIM (nuclear instrument module), to name but a few.
- 3. A good overview figure is needed at the outset, a figure that lays out the entire planning process and shows the interrelationships among the steps. Figure 1 (appearing at the end of Section 3 of this report) is a suggestion for such a figure.
- 4. Figures and tables should be designed so as to reinforce the text, or to help reduce the need for lengthy discussions. For example, Figure 1.1 is particularly helpful in presenting the concept of a Data Life Cycle without a lot of words. In many cases, however, the flow charts and other illustrations or tables are not always particularly useful and are sometimes even confusing, with the important ideas covered better in the text. For example, the text essentially repeats information in Table 3.1 without providing any added value. In these cases, the authors or technical editor should consider deleting one or the other. As an aside, the Panel noted that the text used in the flow charts is too small in many cases and even unreadable in a few cases.
- 5. The MARLAP text is clear about the very non-linear and iterative nature of the planning process, even at its first step. However, this aspect is not reinforced by the figures and tables. Figures 1.2 and 1.3 are static and linear; these figures should include feedback loops to more clearly convey the sense of the process of continual reassessing and fine-tuning the objectives and approaches. The repeating spirals used in MARSSIM's Figure D.2, "Repeated Applications of the DQO [Data Quality Objectives] Process Throughout the Radiation Survey and Site Investigation Process" (MARSSIM, 2000) illustrate one approach for capturing this aspect in a graphic format.
- 6. The draft Manual's Table of Contents indicates that a glossary will be provided. In this glossary, it may be useful to place terms in italics in each definition to indicate those terms that are further defined in the glossary, as has been done in MARSSIM (2000).

3.2.3 Technical Edit

In order to make the Manual more user-friendly, efficient and effective, it should receive a thorough technical edit. The main objectives of this edit should be to remove the considerable amount of redundancy, ensure internal consistency among the chapters in presentation style and formatting, and make wider and more consistent use of effective techniques for presenting information. The Panel found the following presentation and formatting techniques to be particularly effective in emphasizing important points:

- 1. The boxed Summaries of Recommendations at the end of Chapters 2 to 7 and Chapter 9 are useful and easy to understand. However, the number of recommendations for some chapters appears to be too few relative to the large amount of detail given in that chapter. Suggestions for additional recommendations to include in the chapter summaries are provided in Appendix C of this report (e.g., see comments for sections 2.2, 2.3.1, 2.3.3, 2.4, 2.4, 2.5, 2.7.1, 2.7.2 and 3.5).
- 2. The short discussions on uncertainty and error (MARLAP Section 1.4.7), and on precision, bias, and accuracy (MARLAP Section 1.4.8) are admirably concise and focused, saying no more and no less than is appropriate for this introduction to MARLAP terminology.
- 852 3. MARLAP Section 2.2 is another effectively written section, with just the right level of detail, good pacing, and an effective mix of presentation styles (short paragraphs, bulleted lists, boxed example).
- 4. The design and content of Table 2.1 effectively summarizes the planning process and the role of the radioanalytical specialist in this process.
- 5. Although the text in MARLAP Sections 2.5.1 to 2.5.4 covers the same topics as does
 MARLAP Table 2.1, it does not duplicate the table entries but rather adds value beyond
 the information presented in the table. The discussions largely support one another in a
 complementary fashion that is not overly repetitive (although comments in Appendices C
 and D of this report note some discrepancies).
- 6. The specification of inputs and the explicit inclusion of an "Output" statement at the end of the discussion of each Analytical Planning Issue in MARLAP Section 3.3 are very helpful in understanding the value and importance of each item discussed.
- 7. MARLAP Section 3.3.7.1 reinforces critical but subtle guidance by including a short clear example immediately following the paragraph that describes how to establish a Measurement Quality Objective (MQO) for method uncertainty.

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- 8. The well-designed checklist formats used in Chapters 7 and 18 are particularly noteworthy as effective ways to organize and communicate information. Section 7.4.2.2, which addresses on-site audits, is effective in telling the reader what to look for. This approach is equally useful for the laboratory and the client in that it identifies for both parties the key aspects to be examined during an audit and thus facilitates communication between them about expectations. Similarly, the chapter on Laboratory Quality Control (Chapter 18) provides succinct lists of potential causes for specific types of analytical problems, which is an effective way to convey some of the lessons learned from many years of practical experience by the MARLAP co-authors.
- 9. Section 8.5 guides the reader through the data verification and validation process by spelling out the criteria to be met, and the approach to first verify, and then validate, that the data meet the specified criteria. MARLAP is unusual among guidance documents on

laboratory data acquisition in that it clearly distinguishes the different issues to be identified and resolved in the data validation and verification steps.

10. The format used in Chapter 18 subsections is particularly user-friendly: first defining and summarizing the importance of the issue at hand, then expanding on its subtleties in a more extended discussion, briefly mentioning excursions as appropriate, and finally ending with specific examples.

In contrast, reference citations in the document are particularly problematic in the draft Manual, for being incomplete, inconsistent, and sometimes outdated. Federal regulations cited in the text should be included in the list of chapter references so that the reader can judge their potential applicability to specific situations. For example, U.S. Department of Transportation (DOT) regulations may not be applicable to material transport on roads that are closed to public access, such as is commonly the case for some DOE laboratories. To the extent possible, cited references should refer to current editions. Reference citations that include web-site addresses (a practice which the Panel wholeheartedly supports) also need to be checked prior to publication. For example, the web-site address listed for MARSSIM (2000) at the end of Chapters 1 and 3 is incorrect.

Finally, based upon suspected errors found in some equations, the Panel recommends a rigorous check of all equations throughout the Manual in order to ensure that they are correct. Furthermore, the MARLAP Work Group is encouraged to establish a quality assurance/quality control (QA/QC) plan in order to ensure that the equations, tables, and figures do not get corrupted during the process leading to final publication.

3.3 Detailed Comments on Technical Content of Part I

3.3.1 Technical Issues

No significant technical errors were found during the Panel's review. However, the Panel recommends that the MARLAP Work Group consider addressing the following points, at least in a cursory fashion, in the Manual. Additional technical points are raised in Appendix C to this report.

- 1. MARLAP clearly should not be expected to cover every situation involving the collection and evaluation of radioanalytical data, but it might be useful for the Manual to state more clearly and directly the types of decisions to which it applies. Examples of topics beyond its scope include radionuclide speciation in the environment, demonstration of regulatory compliance, and evaluation of some innovative radioanalytical approach, such as for analyzing a short-lived and volatile radionuclide. The Panel refers the MARLAP Work Group to Table 1.1, Scope of MARSSIM, in MARSSIM (2000) as one way to convey information to the reader on the limits of the Manual's coverage. Table 1 in this report suggests the types of entries that may be appropriate for an analogous table in MARLAP.
- 2. Radionuclides released in the environment from a source can be present in different physico-chemical forms varying in size, valence, and charge properties. Although it is

outside the current scope of MARLAP to include specific guidance on analysis of speciation and oxidation states of radionuclides, it nonetheless should discuss the significance of speciation for proper utilization of radioanalytical data. Several radionuclides (e.g., plutonium, americium and uranium) are known to coexist in multiple oxidation states which are each susceptible to different complexation and hydrolytic reactions and consequently, result in different physico-chemical properties. Thus, knowledge about the total concentration of radionuclides in environmental samples is important but may be insufficient to assess potential ecological mobility and risks to humans. Prediction of contaminant transport in the environment can be significantly improved if their physico-chemical associations are well defined. The action level (e.g., the derived concentration guidance level [DCGL]) often, if not always, will be set under the assumption that the nuclide is in the worst possible state as far as risk is concerned (e.g., soluble if the exposure pathway is ingestion). However, if the nuclide is in fact in a different state, then its presence at levels slightly above the action level may be inconsequential. If specified as part of the analytical plan, a laboratory should report the levels of the nuclide in each of its possible states, but in practice, meeting such a request may not be feasible for many radionuclides. Protocols for sample collection and preservation and for speciation measurements are the subject of intense research at the present time. The MARLAP report should acknowledge the importance of this topic and mention the complexities associated with it. The MARLAP authors should be prepared to address the issue of speciation in further detail in future revisions; this effort may require close coordination with the MARSSIM authors on protocols for sample collection and preservation.

- 3. Specific examples of clearly defined DQOs and associated MQOs would be instructive, particularly for illustrating the application of a graded approach. As an example, the Manual could discuss how DQOs and MQOs would differ for analysis of tritium in a liquid sample, depending upon whether the issue being addressed involves site cleanup, drinking water standards, risk analysis, bioassay for worker exposure, leak testing, waste acceptance criteria for a specific treatment facility, effluent monitoring, background survey, or a groundwater tracer study.
- 4. In its discussions of DQOs and MQOs, the Panel suggests that MARLAP include some realistic examples of considerations for developing an optimized strategy using a performance-based approach. The following examples could be used to illustrate that, from the perspective of statistical power, it is often better to obtain many data of only modest quality (e.g., ±30%) than a few data of high quality (e.g., ±1%). (See comments in Appendix C relating to MARLAP Sections 2.5.4, 3.3.1, 6.4, B3.8, and C.3 for suggested locations in which to make this point).
 - a) Data collected for reconnaissance purposes, such as screening an area for hot spots or conducting a preliminary assessment of an area about which little is known.
 - b) Data collected for a purpose that does not require great precision or the prescribed use of a precise method.
 - c) Data collected when it is known or suspected that uncertainties related to field sampling (e.g., representativeness of the sample, sample outgassing) may overwhelm analytical uncertainties.

- d) Calibrated air flow measuring devices on air sampling stations (MARLAP Section 10.5.1, line 1221) offer high precision but maintaining calibrated instruments can be labor-intensive. An alternative which may be a little less accurate, but far more reliable, is to simply measure the flow after placing a new filter on the device and then just before it is removed, and averaging the results. This average flow rate is multiplied by the run time (sampler should be equipped with a simple run-time meter) to get the total flow through the filter. The same flow rate meter, which is taken from station to station and checked frequently for calibration, provides good station to station precision in airflow.
- e) Along similar lines, some guidance would be useful relating to the use of data that do not have a good QA/QC pedigree but that are otherwise believed to be credible.
- 5. The document makes it clear that the radioanalytical specialist is essential throughout the planning, implementation, and assessment phases. However, the skill set for this position differs from that for the generic "health physicist" as described in most job specifications. It thus may be useful for MARLAP to include a sample job specification or Statement of Work (SOW) that could be used by small radioactive materials licensees or small regulatory programs to hire a radioanalytical specialist to help with writing a project-specific SOW, evaluating the bids, and assessing the data. In addition, the Manual should note areas in which individuals with related backgrounds could also conduct some of the tasks, noting that the role of the "radioanalytical specialist" need not be filled by a single person with a specific title but rather may be jointly covered by the expertise and experience of the other team members, e.g., industrial hygienist, laboratory personnel, scientist, project manager.
- 6. Timely review of data packages is a very important point that cannot be emphasized enough. Without feedback from this review process, the whole process could suffer because needed changes would not be identified in a timely or effective manner. Although stated clearly in MARLAP Section 5.4.3.3, this recommendation should be reiterated in the summary section of that chapter as well as in Chapter 8.
- 7. The Panel agrees with the approach taken by the authors to seek and identify points on which consensus could be reached, such as an overall approach (or structure or framework) to be taken rather than details on the specific steps or the order in which they should be taken. Nonetheless, it would be useful for the Manual to openly acknowledge that many areas exist in which agency guidance or requirements are currently not uniform or consistent, such as in the establishment of action levels, reporting uncertainties, assessment of penalties if specifications are not met by the contracted laboratory, differences in number of significant figures reported, attention given to estimating yields, and treatment of negative data.
- 8. There is a need to check generalizations that may not apply to a significant proportion of the target audience or to the samples with which they may be dealing, and to assess whether exceptions to these generalizations are sufficiently important to warrant at least a brief mention. Several examples are given from Chapter 11:

- a) Guidance on line 207 of page 11-8 is to treat contaminated packing material and packages as radioactive waste; however the possibility that there may be non-radioactive hazardous contaminants that would require the contaminated material to be classified as mixed waste is not mentioned.
 - b) Similarly, page 11-6 seems to mandate a designated receiving location for all samples, and page 11-14 states that sample storage areas must be posted as Radioactive Materials storage areas. For small projects or those limited to the analysis of very low levels of radioactivity, these apparent "mandates" may not be applicable or may even be counter-productive (e.g., by storing low-level samples together with high-level samples).
 - c) Page 11-4 (lines 73-75) states that laboratory facilities that handle radioactive materials are required to have a radioactive materials license issued by the NRC or the Agreement State in which the laboratory operates, with the exception of certain DOE and DoD laboratories. However, it is important to make clear that the latter facilities themselves cannot handle unrestricted levels of radioactive materials. They operate under similar types of regulation-driven restrictions, which are administered internally.
- 9. Chapter 9 of the Manual focuses on verification, validation, and assessment of the laboratory measurements. Somewhere in that chapter, perhaps in Section 9.2, the selection of the verification, validation, and assessment personnel should be discussed. Can some of them come from the performing laboratory? From the sponsoring organization (e.g., EPA, DOE, or DoD)? From the financially responsible parties? From an outside organization contracted to do the work? What qualifications are essential?
- 10. The example on page 3-16 (lines 458 ff) implies that data are unacceptable if the uncertainty does not meet the à priori MQO. This is not necessarily the case. For example, if an action level is 0.1 Bq/g (as in the MARLAP example), the uncertainty should be less than 0.01 Bq/g. However, data for a sample with a concentration of 0.02 Bq/g and an uncertainty of 0.02 Bq/g are still valid and useful even though the reported uncertainty exceeds the MQO of 0.01 Bq/g. The MARLAP should make a distinction between the à priori MOO and the validity of the actual data.

3.3.2 Use of Examples

More examples are needed to illustrate the planning process and the graded approach, so as to bring these to life for the reader. A variety of clearly presented and realistic scenarios will be critical to the success of MARLAP and should emphasize the potential benefits of planning and using a graded approach. The Panel suggests the following aspects be considered for adding more examples:

1. References to good examples of process outputs (e.g., Statements of Work) from different agencies would be helpful. Specific examples or case studies would also be helpful, such as how to analyze a volumetrically-contaminated sample (e.g., scrap metal) in order to

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- decide its disposition. Specific scenarios or case studies could be carried through each chapter to illustrate and contrast how a particular step would be implemented in those particular cases.
- 2. The MARLAP process appears to be designed for, and is applicable to, large projects encompassing a team and a relatively large number of samples. However, it is not clear that it would be practical to implement for small projects. Although the document refers to a graded approach, insufficient explicit guidance is provided for small projects. The detailed process described in the MARLAP Manual requires intensive use of resources. This is appropriate for large-scale environmental projects but not for small-scale evaluations and other activities. Therefore, it would be useful if the Manual could advise users on circumstances for which a much simpler approach would be appropriate, e.g., similar to the brief example discussed in Appendix B in MARSSIM (2000), which applies to certain users of sealed sources, short half-life materials, and small quantities. The limited number of references to a "graded approach" in MARLAP (e.g., Sections 2.3.1 and 4.5.3, and the first recommendation on p. 4-18) do not provide guidance that is clear or complete. For example, the Manual could expand upon its statement in Section 2.3.1 that the concept of a graded approach extends to the representation of the planning team by using this opportunity to provide a couple concrete examples of simple activities in which only a few people would need to be involved in the planning. Examples of the graded approach could also be provided in the discussion on selection of contract services (Appendix E).
- 3. The federal MARLAP Work Group should consider whether a simpler version of MARLAP could be prepared, that would be applicable to the \$10,000 to \$50,000 projects that involve taking no more than 10 to 20 samples and that cover a small area. This is an important point. Regulatory agencies may try to apply the entire MARLAP process to situations and organizations for which a full-scale effort would not be appropriate. Some "out" must be available for small projects that are being required to respond to radiological situations with minimal potential for real impact. Suppose, for example, an entity had a small site with the potential for very low levels of contamination. This type of project could be a short-term decommissioning project, involving a health physicist and a couple field and laboratory personnel. The health physicist would be responsible for site safety as well as the development of the sampling and analysis plan and production of the final report. The entire budget could be expended in writing the Project Plans described in MARLAP. A simpler outline could be developed that would give reasonable assurance that the DQOs would be met but without the myriad of written plans and reviews. A limited version of MARLAP could cover the development of DOOs, sampling and analysis plans, and verification and validation of data, but would not necessarily go into great detail in the selection and evaluation of a laboratory. Contract laboratories can be selected just on the basis of past experience.
- 4. The Panel recognizes that policies are often implied in the assumptions that are adopted as part of the planning process, and that it is difficult for a multi-agency document to address this non-technical aspect. The Panel also recognizes the concern of the federal MARLAP

1106	Work Group that case studies or scenarios could be interpreted by some users as setting or
1107	endorsing a precedent. However, the Panel recommends that this concern be addressed
1108	upfront and that the MARLAP Work Group not be discouraged from including realistic or
1109	complex case studies or scenarios in the Manual.



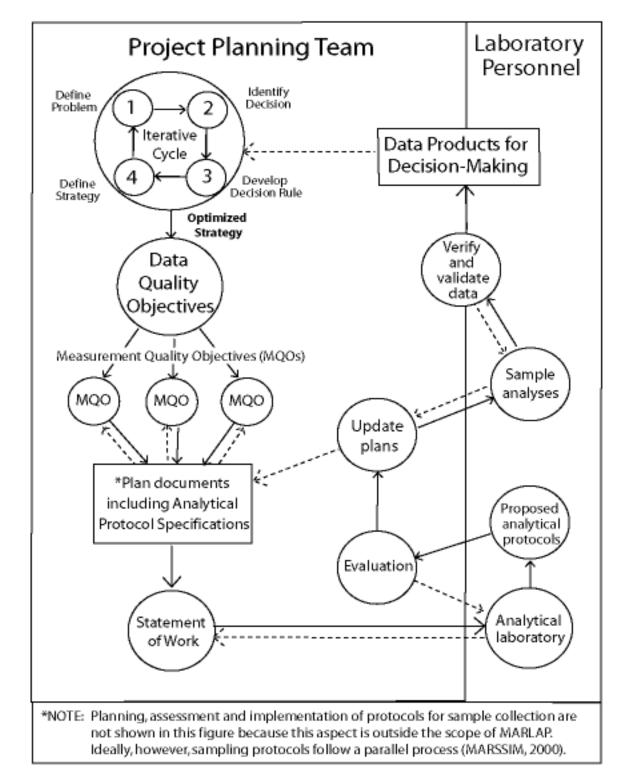


Figure 1. Schematic of the MARLAP planning, assessment and implementation process for radioanalytical analyses. Solid arrows indicate advancement to the next step, while dotted arrows indicate feedback loops to earlier steps.

Table 1. Scope of MARLAP

Topic Within Scope of MARLAP **Beyond Scope of MARLAP** Describes an approach that is Regulatory guidance Does not establish or propose new regulations generally consistent with those for radioanalytical protocols required by various federal and state Does not address how to demonstrate agencies responsible for managing compliance with regulations radiological contamination Applicability to specific Broadly applicable to any project Does not specify whether or not MARLAP is projects requiring the acquisition of applicable to a specific project radioanalytical data. Not intended to address research and Emphasizes a "graded approach" development projects requiring acquisition of to data acquisition, in which the radioanalytical data extent of application is based on Would be difficult to apply to pre-existing the intended use of the data and data, in the absence of detailed information on the degree of confidence needed the protocols used for sampling and analysis in the quality of the results Applicable to any radionuclide for Contaminants of Does not address analytical protocols for which action levels are, or can concern nonradioactive chemical constituents be, defined Does not address the determination of radionuclide speciation or oxidation state May be difficult to apply to a radionuclide for which an action level does not exist or is irrelevant (e.g., studies of groundwater recharge and solute transport rates based on concentrations of natural atmospheric radionuclides like tritium or carbon-14) Does not provide detailed guidance on sample Sampling procedures Discusses how sampling protocols can affect the analytical results collection Addresses analytical issues for a Types of media Does not contain guidance on sampling or wide range of media typically analyzing fixed contamination on surfaces, encountered in environmental i.e., radioactive contamination that cannot be sampling studies readily removed from surfaces by nondestructive means such as wiping or washing 1123 Does not provide prescriptive or default DOO or Data Quality Objectives Presents a systematic approach for 1124 MQO values (DOOs) and developing qualitative and 1125 Measurement quantitative statements of the 1126 Quality Objectives analytical data requirements for 1127 (MQOs) a project 1128 Action levels Describes how action levels are used Assumes that action levels will be provided rather to establish quantitative data than specified by MARLAP requirements adequate to support decisions

	Topic	Within Scope of MARLAP	Beyond Scope of MARLAP
1129	Analytical procedures	Guidance given in MARLAP is performance-based and directed towards acquiring data adequate to meet a project's specific data needs. The Manual should be viewed as a toolbox with many components—some of which are discussed explicitly in MARLAP and others by reference.	 Does not contain step-by-step descriptions of analytical procedures Does not recommend the use of specific analytical equipment or procedures Does not include novel analytical procedures that are not yet widely accepted by the radioanalytical community Does not establish specific procedures for sample storage and disposal Does not contain guidance on the analysis of fixed contamination on surfaces Provides only cursory discussions on laboratory health and safety, and waste management
1130	Use of analytical data	Discusses how to translate a decision into a testable hypothesis with an associated decision error rate, and provides a set of statistical tests for evaluating data against the stated hypothesis	 Does not discuss how measured data are translated into doses or risks Does not discuss how measured data are compared against release criteria for contaminated components, equipment or property Does not recommend the use of specific hypotheses, decision error rates, or statistical tests
1131	Non-technical issues	Recognizes that non-technical factors (e.g., costs, stakeholder concerns) can impact the selection of analytical protocols	 Does not discuss non-technical issues (e.g., legal or policy) in detail Does not address public involvement Does not address training issues for analytical protocols
1132			

4. RESPONSE TO CHARGE QUESTION #2: TECHNICAL ACCURACY OF GUIDANCE ON LABORATORY OPERATIONS

<u>Charge Question #2</u>: Is the guidance on laboratory operations in the Part II chapters technically accurate? Does it provide a useful resource base of information for a laboratory's implementation of a performance-based approach?

4.1 Overall Response to Charge Question #2

MARLAP is an impressive compilation of information and recommendations that should be immensely useful to radiochemical analysis practitioners. The document addresses the entire reach of radiochemical analysis from project design to final report of results. Each section appears to have been prepared by competent specialists in the topic, and little appears to have been ignored or misinterpreted. The MARLAP document matches the MARSSIM document for providing guidance for the laboratory analyses of field samples collected under the MARSSIM approach.

The following discussion focuses on Chapters 10 to 20 (excluding Chapter 19) of Part II because they specifically discuss the actual laboratory operations of analytical processing and measurement. Because these chapters are integrated into the entire text, some comments refer to related aspects in other chapters. On the whole, guidance in these chapters is reliable and well thought out. However, as would be expected for such a large document, the Panel found numerous errors. While many of the errors are typographical, they can be misleading, such as errors involving a chemical formula or technical terminology. Suggested corrections are compiled in Appendices C and D of this report.

The document is an encyclopedic resource. Chapters 10, 11, 12, 16, 18 and 20 are particularly well written, technically straightforward, and very useful. For the sake of clarity, Chapters 13 and 15 require more important revisions because some of the information is either incomplete, not useful or repetitious. Most of the suggested changes are organizational or editorial in nature, although they affect the technical clarity of the document and its internal consistency. Specific parts that would benefit from revisions are identified in Section 4.3 of this report.

The Panel concludes that the performance-based approach for the MARLAP document is appropriate and presented clearly and logically. The Panel suggests some reorganization of the presentation to the user, as described in recommendations provided in this review. Subject to the caveats listed in this section, Part II of the MARLAP document provides a much needed resource base for laboratory operations.

The Panel spent considerable time discussing the issue of how to report measured values that are below the minimum detectable concentration (MDC) as determined from counting statistics or even negative (due in the latter case to the subtraction of non-negligible background concentrations). The Panel agrees with the MARLAP authors that the laboratory must report "as measured" values, whether or not negative or below the MDC, in the product intended for the

scientists who will compile and statistically analyze the results for decision-making and who must evaluate the reliability of measurements near the limit of detection. The Panel was divided on the issue as to whether or not the lay public and nontechnical decision makers would be better served by tables that use "less than" values or statements of nondetectability for such measurements, in order to provide a better picture of the prevalence of results reliably different from zero. Reporting in that form will seem more familiar to many users, and doing so also eliminates the need to explain why the laboratory appears to have measured a physically impossible value. However, several Panel members strongly objected to the proposal to "dumb down" results for managers and the public. That practice increases the likelihood that the non-numeric results will be misused in further analyses and decisions, including the danger of generating mixed data sets with inconsistent treatment of low-level measurements. The Panel recommends that the MARLAP Manual address this issue in more depth and attempt to find a solution that will allow reports to the public and decision makers to be easily understood without being easily misused. A compromise solution to this quandary is proposed in Section 5.3.2 of this report.

The Panel also discussed the relationship of uncertainties in the results of laboratory analyses with the generally much larger uncertainties associated with:

- 1. derivation of an action level (e.g., a DCGL) from a risk-reduction policy goal, and
- 2. design of an effective sampling strategy to decide whether the action level is exceeded.

The federal MARLAP Work Group made it clear orally that its intent was to specify analytical procedures whose uncertainties would not add significantly to the uncertainties from other steps of the decision process. To the Panel, that intent is less clear in the written Manual, and it should be clarified there, perhaps in what is now Section B-1.3. Moreover, some Panel members are concerned that the Manual's definition of "significant" might inhibit strategic tradeoffs between the precision of the analytical procedures and the coverage of the sampling plan. These two steps compete for resources; whether larger sample size with less analytical precision or smaller sample size with greater analytical precision is best for a given situation undoubtedly depends on situation-specific factors. Again, the Manual should devote greater attention to this issue, perhaps in Section B-1.3 and possibly in Section 1.4.7 as well.

In summary, guidance to the designers and managers of analytical laboratory projects should be as complete and direct as possible to avoid misuse of the MARLAP process. The Panel strongly supports the initiation and maintenance of a training program and implementation of a web site to enhance dissemination of the points raised above, as well as others.

The MARLAP Manual should emphasize the identification and treatment of data that are crucial for making decisions. Analyses that influence the overall performance results should be evaluated and, if necessary, redone prior to the completion of the decision process. Similarly, this point could also apply to the selection of the null hypothesis. This issue needs to be addressed in more detail in MARLAP. The most conservative approach may not be the correct one. Failure to thoroughly evaluate the null hypothesis in the early stages of a project may lead to the wrong policy decisions, i.e., that a relatively "benign" site requires remediation. The Panel expects that

this and other aspects of the technical implementation of MARLAP's performance-based approach will be greatly improved by user feedback as the document is tested through time.

4.2 Detailed Comments on Organization and Presentation of Part II

The Panel suggests that Part II be divided into two parts to facilitate convenient use in the laboratory. A reasonable separation may be between Chapters 10 to 14 and Chapters 15 to 20. Dividing Part II into two parts would make the document more convenient for use by radiochemists and by radiation detection and quantification users. Such a division would also help with the unwieldy physical size of the document in its present form, and in locating the needed information more quickly by the users. This suggested logical division is described in more detail below.

<u>Part IIa. Chapters 10 to 14.</u> These chapters contain information on sampling considerations, sample receipt and inspection on laboratory premises, sample preparation and pretreatment, and various separation techniques. All these topics are related and are likely to be used mainly by the radiochemistry laboratory staff (except possibly Chapter 10, Field and Sampling Issues).

<u>Part IIb. Chapters 15 to 20.</u> The remainder of the document, i.e., Chapters 15 to 20, includes information on nuclear counting, instrumentation, calibration and test sources, data acquisition and reporting, quality control, statistical considerations, and waste management. These topics are somewhat related (except Chapters 19 and 20, which are stand-alone chapters) and are likely to be used mainly by the counting laboratory staff.

Appendices should be rearranged for inclusion with the respective volumes, so as to facilitate the ease of use. At present, all appendices for Parts I and II are placed at the end of Part II.

4.3 Detailed Comments on Technical Content of Part II

Note: Additional comments related to these chapters are compiled in Appendices C and D. Some of these specifically address complexities associated with analytical methods and techniques.

4.3.1 Chapter 10: Field and Sampling Issues That Affect Laboratory Measurement

Overall this chapter is straightforward and useful. Although not necessarily a bad thing, a disproportionate amount of space is devoted to radon. It is all good information, but invites the question why there are not analogous sections such as "Selecting Tritium Sampling Methods Based on Data Quality Objectives" or for any other radionuclide as well? A table summarizing the known problems related to container and type of acid preservative for the various radionuclides, matrices, and analytical methods would be a useful addition to Chapter 10. For example, USGS documents usually indicate hydrochloric acid rather than nitric acid as a preservative for water. Is there a good reason for this? [Note: These sampling concerns could

logically be addressed in either Sections 10.3.3.1 or 14.10.9.]

Several instances are noted in which the compilation of sampling methods or sampling data needs is incomplete:

Section 10.4.1. The Manual should remind users that the laboratory needs to document the amount of vegetative material removed from a sample so that environmental concentrations can be estimated appropriately for the exposure scenario(s) of interest. Also, sampling soil profiles and sediment cores for determining total inventory is an important technique that is not presented in this section of MARLAP. For example: soil at specified depths can be removed and analyzed separately. A plot of activity as a function of depth can be prepared, and the activity integrated over a particular depth of soil can be determined [c.f. DOE (1990)].

<u>Section 10.4.2.1.</u> This section implies total reliance on models for description of initial mixing and transport dispersion of radionuclides discharged to water. The use of dyes or other tracers in studies of complex situations should be acknowledged.

Section 10.4.3.2. In selecting foods and locations for food sampling, it is tempting to limit consideration of consumption habits to those of European-descended populations. The consumption and lifestyle habits of native peoples and other ethnic minorities can be quite different. MARLAP should recommend consideration of these differences. The use of inedible plants and non-game species as indicator organisms should also be mentioned in this section.

<u>Section 10.5.4.2.</u> Noble gases in air have also been collected for laboratory analysis by compressing air into SCBA tanks, by collecting in impermeable plastic bladders (e.g., Tedlar) for later compression, or by cryogenic methods. Radon isotopes do not present an issue as interferents if laboratory analysis is delayed sufficiently for their decay.

Section 10.5.4.3. Electrets can also be used for monitoring tritium at relatively high levels. The use of electrets was discussed with regard to radon so a discussion of that technology in the tritium section would also be appropriate (e.g., Surette and Wood, 1993). Although mentioned earlier, the molecular sieve technique is not identified as a method for collecting tritium. Molecular sieves are being used increasingly because of favorable properties such as less water retention following bakeout and better collection properties in environments with fluctuating temperatures.

<u>Section 10.5.5.2.</u> Methods for measuring radon flux should be mentioned in this section. In addition, ²²⁰Rn analysis methods should be addressed. Also, it would be appropriate to note here that MARSSIM Section 6.9 provides extensive guidance on radon measurement methods and instrumentation.

<u>Section 10.6.2.</u> It would be very useful to indicate or reference suitable combinations of liquid scintillation fluids (cocktails) and filters for the liquid scintillation method of wipe testing.

The Panel also notes an exception to the general guidance provided on labeling of samples submitted to analytical laboratories. The statement in Section 10.2.4 (lines 173-176) provides

- guidance on ensuring that laboratory data are not influenced by prior knowledge of the origins of the samples. This is certainly an important consideration and needs to be discussed. However, the wording implies, perhaps unfairly, that laboratory personnel might take deliberate actions in this regard. In addition, there are many situations in which a laboratory would need to be aware of samples with relatively high levels of activity as these may require separate treatment to prevent cross-contamination, as is reflected in the statement on lines 313-314 in Section 12.2.4. The statement in Section 10.2.4 could be reworded as follows: "The project manager needs to determine whether the sample numbering scheme is appropriate. It is advantageous to number samples to be submitted to a laboratory in such a way as to prevent inadvertent bias on the part of the analyst. However, in some cases, laboratories need to be aware of "hot" samples because these may require the use of separate areas or labware for processing (see Section 12.2.4)."
 - Some technical inaccuracies in guidance or in generalizations are noted in this chapter:
- Page 10-8, lines 217-219. The time to date of analysis is usually captured in pre-established holding times, not left to the judgment of field sampling personnel who make entries in the log or on the data form.
- Page 10-21, lines 660-661. "...radionuclides that are highly insoluble, such as isotopes of uranium, thorium, and plutonium..." This is an invalid premise. Uranium is somewhat soluble and occurs dissolved in some groundwaters. Thorium and plutonium are better described as relatively immobile in the environment rather than insoluble, because thorium nitrate, for example, is certainly soluble.
- Page 10-24, line 766. The statement "...paper pulp has been shown to remove more than 95 percent of radionuclides from solution..." seems too general. Tritium, for example, would not likely be removed by paper pulp.
 - Page 10-27, line 839. The following sentence is much too simplistic as guidance for selecting milk sampling sites: "Raw milk should be obtained from the closest cows or goats downwind from a source." For example, background sites should also be selected, and processed milk may have to be collected to fully characterize the impact on the general public. Significant iodine releases are much more likely to result from accidental exposures, which may be short term, than from continuous routine releases. Relying on a single "downwind" sampling location could potentially result in underestimating the impact of an episodic event.

4.3.2 Chapter 11: Sample Receipt, Inspection and Tracking

The relationships among various recommended documentation (e.g., bench sheets, laboratory logbook, "separate paperwork obtained before sample receipt," and "documents listing requests for specific analyses") need to be made clear. Good examples of these documents would be useful.

4.3.3 Chapter 12: Laboratory Sample Preparation

Overall, this chapter is straightforward and useful. Note that tritium may also be a problem for cross-contamination if low-level measurements are made in an environment where higher-level tritium sources are analyzed or in use. Tritium from leaking exit signs may also be a problem in certain laboratories. Similarly, background levels of radon progeny from natural sources in soil or possibly in the building's construction materials may create a problem in low-level counting laboratories. Short-lived radon decay products can become attached to surfaces, particularly where a static charge has been induced.

4.3.4 Chapter 13: Sample Dissolution.

In general, this chapter should be reorganized so as to discuss the issues from the simplest to the most complex. In addition, Section 13.6 (Special Matrix Considerations), Section 13.7 (Total Dissolution and Leaching), and Section 13.8 (Examples of Decomposition Procedures) should be presented differently. The style in these sections is inconsistent, and the text is either too general or overly specific with direct quotes from published papers. An alternative approach would be to refer the reader to specific publications for each special case.

4.3.5 Chapter 14: Separation Techniques

A table summarizing the characteristics of alpha, beta, and gamma radiation should be inserted at the beginning of Section 14.2 to illustrate that the extent of radiochemical separation is impacted, in part, by the type of radionuclide emission (e.g., see Table 2 as an example of such a table). This information relates directly to the understanding of the required chemical separation for each type of emission.

Table 2. General Characteristics of Alpha, Beta and Gamma Radiation

Characteristic	Alpha	Beta Particles	Gamma Radiation (Photons)
	Particles		
Identity	Helium nuclei	Electrons	High-energy electromagnetic
		Positrons	radiation (e.g., gamma or x-
			rays)
Mass (g)	~10 ⁻²⁴	~10 ⁻²⁸	0
Charge	2+	1±	0
Energy characteristic (initial emission	Discrete	Continuous or	Discrete
energy)		discrete	
Penetrating power (relative)	1	100	10,000
Required radiochemical separation	Extensive	Modest	Minimal or not required

Section 14.10 would benefit from some reorganization and revised headings. This section would be more appropriately titled "Analysis of Specific Radionuclides," which is its subject, rather than "Radiochemical Equilibrium," which does not describe its contents. The presentation would be better balanced by placing current Sections 14.10.1 to 14.10.8 as subheadings in a new Section 14.10.1 called "Introduction" or "Overview." This overview should also include a brief

explanation concerning the selection of the specific radionuclides that follow. The selection makes sense but should be justified. Finally, the analytical aspects of individual radionuclides in current Sections 14.10.9.1 to 14.10.9.12 would be renumbered as Sections 14.10.2 to 14.10.13.

The citation of references in subsections 14.10.9.1 through 14.10.9.12 is problematic for the Manual's users. Each of these 12 subsections has 8 sub-subsections, beginning with "Isotopes" and ending with "Methods of Analysis." The properties of radionuclides that permit chemical separation are discussed throughout these sub-subsections, but the references that underlie the presentation for each radionuclide are all bunched in the last sub-subsection, "Methods of Analysis." It would be far more convenient for the reader if each discussion of a property that permits separation and purification were associated with the reference on which it is based. At present, the reader who wants to follow up a particular separation has to guess which of the references are pertinent. This comment pertains to each of the 12 subsections.

Detailed descriptions of certain aspects of chemical behavior in current Sections 14.10.1 to 14.10.8 should be referred to in the specific radionuclide sections to avoid repetition concerning matters such as hydrolysis and polymerization. For specific radionuclides discussed in Section 14.10.9, extensive paragraphs that describe the occurrence, properties, and preparation of minerals and the metallic state should be deleted unless they are pertinent to the purpose at hand. Furthermore, some of the discussion on the environmental behaviors of specific radioelements such as plutonium and uranium is misleading and overly generalized (see specific comments in Appendix C of this report, relating to Section 14.10.9). For such topics, it might be best to direct the reader to appropriate up-to-date references rather than to provide detailed descriptions of aspects that are largely outside the scope of MARLAP. Similarly, the discussion of toxicity and radiotoxicity in Section 14.10.9 is not appropriate except when advising on sample handling, in which case any warning to analysts should include specific information about use, quantity, and speciation in order to place amounts and effects in perspective. If the reference to toxicity is intended to explain the purpose or required sensitivity of an analysis, the reader should be referred to a radiation protection text. In a large tome such as this, the authors should limit themselves to pertinent information.

4.3.6 Chapter 15: Nuclear Counting Instrumentation

This chapter is a strange presentation of two writing styles: Sections 15.2 to 15.6 and Sections 15.7 to 15.10. In addition, much of the material in the first part is repeated in the second part. Although this chapter is admirably concise, it (especially Sections 15.2 to 15.7) is not consistent with the rest of MARLAP, which is much more detailed. Because of its conciseness, there is missing information in parts of the chapter. This material appears later in the chapter and even in Chapter 16 but there needs to be a better organization. The Panel learned that the reason that Chapter 15 is confusing and/or repetitive is because at least part of it was taken directly (and with permission) from an American Society for Testing and Materials (ASTM) text, but its order was reversed. This chapter needs to be rewritten. The material in Chapter 15 would be more efficiently presented if it were to describe proportional counters and scintillation counters (or even each of the various types of detectors) first and then describe specific radiation types. This reordering of material would avoid the need to repeat the description for each type of radiation.

Section 15.7 is redundant with much of the early material but is written more in the style of the rest of MARLAP. This section answers many of the questions raised in reading the earlier sections. It might be worthwhile for the earlier sections to be merged into section 15.7. Perhaps much of the overlap and difference in presentation in this chapter could be overcome by reorganizing the chapter. Starting on page 15-26, the chapter reads very well. This section should be used as a guideline for the earlier parts of the chapter. Pages 15-31 and 32 are redundant with Chapter 16 and should be deleted. On page 15-39, the writing suddenly becomes very specific and prescriptive. Consider whether some of the material in Attachment 15A, "Field Measurements," is redundant with other chapters on calibration or quality assurance.

The federal MARLAP Work Group should review Chapter 15 to be sure that the terminology used is consistent with current practices. For example, in Section 15.2 (lines 133 ff), photomultiplier tubes are referred to as "multiplier phototubes." This is not the usual terminology and is jarring to the reader.

4.3.7 Chapter 16: Instrument Calibration and Test Source Preparation

Chapter 16 seems to be straightforward and unambiguous with a good balance between the general performance and the prescriptive. There are numerous reference citations. Some of the instrument descriptions in this chapter are better than the ones in Chapter 15. There are instances of overlap with other chapters; and although this repetition probably cannot be avoided, it is suggested that a better integration of Chapters 12, 13, 15 and 16 be sought. This may be accomplished in part by including suitable references in the chapters preceding pertinent discussions in Chapter 16. In general, a better "road map" to these chapters is required for clarity.

Chapter 16 deals with two topics, instrument calibration and test source preparation. Because instrument calibration is intimately linked to Nuclear Counting Instrumentation (Chapter 15), the question arises as to whether this topic should be included in Chapter 15 instead of Chapter 16. In contrast, test source preparation deals with converting the collected and processed samples to a suitable form for introduction to the counting instrument; hence, this topic is the bridge to Chapter 15 from:

- 1. Chapter 12, Laboratory Sample Preparation (for samples that need minimal preparation),
- 2. Chapter 13, Sample Dissolution (for samples that need moderate preparation), and
- 3. Chapter 14, Separation Techniques (for samples that need radiochemical preparation).

The Panel suggests that the federal MARLAP Work Group consider making Test Source Preparation a separate chapter either before or following the current Chapter 15. The common thread between the two parts of Chapter 16 (instrument calibration and test source preparation) is that both the test samples and the calibration samples should be prepared in the same, consistent manner. These two topics could be separated, with a note in the test source preparation chapter that samples need to be consistent for the calibration to apply to all the samples. A note could also be inserted in the calibration section stating that the calibration sources need to simulate the geometry and composition of the test samples. The chapter as written flows well and it currently uses some of the material already introduced in Chapter 15. At a minimum, the document should

be reviewed to ensure that the wording in Chapters 12, 13, and 14 and at the beginning of the Test Sample Preparation part of Chapter 16 recognizes and facilitates the linkages described above.

It is not clear what the role for commercial, plated alpha and beta sources is, particularly for alpha spectrometry. MARLAP should discuss the considerations, cautions, correction factors, etc. should a laboratory choose to purchase commercial sources rather than custom making sources from calibrated solutions.

4.3.8 Chapter 17: Data Acquisition, Reduction and Reporting

In general, the text is very well written, with the exception of some repetitions and redundancies and editorial points as listed in Appendices C and D of this report. The Panel compliments the authors on the thorough technical job done for this chapter.

One shortcoming is that the advice to laboratories on how to check their own data is not adequate (discussed in Sections 7.3 and 7.4 and tie-in of Chapter 17 with Chapters 8 and 9). MARLAP presents consumer advice on how to verify and validate data, but provides no parallel advice to laboratories on how to check their own data. Verification is possible but not validation. MARLAP should provide advice on data verification by the laboratory as well as by the consumer.

4.3.9 Chapter 18: Laboratory Quality Control

This chapter is very well written and the presentation of the material is very accessible. The Panel compliments the authors for the thorough technical presentations in this chapter. The MARLAP authors might want to include the International Atomic Energy Agency (IAEA) along with NIST as a source of certified reference materials [IAEA Analytical Quality Control Services (AQCS), 2002].

The greatest problem resides in the presentation of the references in the text, which should be accompanied by a date of publication to distinguish these from earlier versions of the same documents. The reference section needs work and the format needs to be consistent throughout the section as well as throughout the MARLAP document (i.e., from chapter to chapter).

Attachments 18A and 18B are very useful additions to Section 18.3.2, "Statistical Means of Evaluating Performance Indicators--Control Charts." Attachment 18A serves as a guide to the various control charts and their use in the statistical evaluation of data sets. The solutions to the problems given in the section should be verified using an internal QA procedure for all statistical and numerical problems and equations throughout the MARLAP document. The only problem noted in Attachment 18B is the equation indexing. Problems and their solutions are well presented and the section is very useful as an illustration of additional statistical methods available to the user of control charts.

NOTE: The Panel's comments on **Chapter 19** are addressed under Charge Question #3 in Section 5 of this report.

15381539 4.3.10 Chapter 20: Waste Management in a Radioanalytical Laboratory

 The chapter has good flow and is well written. The second paragraph in the introduction is a nice road map that tells what the chapter is all about. The chapter, out of necessity, gives general guidelines and then lists specific references to lead readers to more detailed information. Section 20.8, "Useful Web Sites," is an excellent addition to the chapter. However, just before final publication someone should verify that these sites are all still correct and active.

5. RESPONSE TO CHARGE QUESTION #3: GUIDANCE ON MEASUREMENT STATISTICS

<u>Charge Question #3</u>: Is the guidance on measurement statistics - specifically measurement uncertainty and detection and quantification capability - technically accurate, clearly presented, and useful for implementation by appropriately trained personnel?

5.1 Overall Response to Charge Question #3

The Panel finds that the issue of measurement statistics is addressed very well but could benefit from some revision in specific areas (described below) to enhance its value to laboratory directors and staff. Review comments on Chapter 19 and its attachments have been divided into four areas: organization, terminology, technical issues, and use of examples. The comments that follow represent a consensus on issues addressed by the Panel members.

5.2 Detailed Comments on Organization and Presentation of Chapter 19

5.2.1 Organization

Overall the Panel finds that too much material is included in Chapter 19, and that the material is not presented in the most logical order. The Panel suggests several changes to address these problems:

- 1. Divide the chapter into two sections. The simpler concepts of measurement, detection, and quantification should be discussed in the first section, followed by a section on the more complex issues regarding uncertainty evaluation and expression.
- 2. Provide the most important material at the beginning of the chapter. For example, there is a good discussion of counting statistics starting on page 19-44. This discussion should be moved to (or near to) the start of Chapter 19.
- 3. Attachment 19E contains some good examples. These examples should be brought into the body of the text in appropriate places.
- 4. Avoid duplication of examples (e.g., the example on page 19-121 is an exact duplicate of the one on page 19-69).
- 5. Number the examples to facilitate reference in the text.
- 6. Bullet the important points in boxes. The box on the top of page 19-25 is a good example. It is, however, critical that these boxed "important points" be clear. For example, the box on 19-25 states: "A measurement result should not be compared to the minimum detectable concentration to make an analyte detection decision. A detection decision may be made by comparing the gross signal, net signal, or measured analyte concentration to its corresponding critical value." This important recommendation should also be

- illustrated at this point by an example.
- 7. Eliminate Attachment 19B, "Multicomponent Analyses."

5.2.2 Terminology

The Panel finds the technical presentation to be statistically sound but too complex for the target audience of laboratory directors and staff. This chapter and several of the attachments would be more understandable to non-statisticians if an attempt were made to use more colloquial language for presentations of concepts that will be easier to understand by the target audience. For example, the presentation of statistical independence vs. correlation provided on page 19-5, lines 122-127, is unnecessarily complicated and probably not needed. Similarly, Attachment 19C on coverage factors should either be deleted or revised. As currently written, it is doubtful that anyone without a Ph.D. in statistics and with experience in laboratory uncertainty analysis could

implement this methodology.

Many of the terms used in the measurement statistics chapter may be commonly employed in the jargon of laboratory science, but these terms are confusing when read by statisticians. The Panel recognizes that this is a deliberate attempt to distinguish some of the less rigorous concepts involving laboratory uncertainty from those employed in a more strict statistical interpretation. Examples are "standard uncertainty" for "standard deviation" and "coverage factor" for "uncertainty interval" or "confidence interval". For example, on page 19-10, lines 240-241, a statement is made that: "The uncertainty in x is expressed in the form of a standard deviation, called the standard uncertainty...". However, on page 19-29, the standard uncertainty of an input estimate using the sample mean of n observations is given in equation 19.4 as the standard error, which is the standard deviation of a mean of size n. Therefore it is not clear whether the original definition of standard uncertainty is intended to mean the standard deviation of the distribution (which does not depend upon sample size) or the standard error, i.e. standard deviation of a sample statistic which does depend upon the sample size. Perhaps what should be stated is that the standard uncertainty is the standard deviation of whatever statistic is chosen as an estimator of the input parameter as actually used in the analytic method, i.e. do not use the standard error of a mean of size n if the method only uses one replicate for that input parameter.

The MARLAP Manual frequently uses the word "uncertainty" to describe the inability of any procedure to measure some value exactly. Sometimes, however, a decision depends on the true variability of values for a parameter, as with variable soil concentrations over a contaminated site. In that case, the important uncertainty may be about the value of, say, the mean, and depends on the sampling strategy as well as the analytic procedure. Moreover, the variability of measurement results over a set of nominally identical samples can be used to characterize the uncertainty in the next measurement of a similar type of sample, and the variability of measurement results over samples taken from a site can be used to characterize the uncertainty about the mean soil concentration over that site. The MARLAP Work Group surely recognizes such distinctions between uncertainty and variability. The Panel recommends that the distinction be discussed early in the document, perhaps directing the reader to a more detailed discussion later, for example in Chapter 19.

1633 eff 1634 eva 1635 ref 1636 jud

Other examples include vague definitions of "Type B" evaluations and counting efficiency. Although strictly correct, the former term should not simply be defined as "any evaluation of standard uncertainty that is not a Type A evaluation", but rather should include a reference and a more helpful statement that Type B evaluations are typically based upon expert judgment. Similarly, counting efficiency should be defined in terms such as the ratio of analyte measured to the amount of analyte present.

The Panel realizes that the MARLAP Manual is directed at laboratory personnel who may be familiar with the terminology used in the current version. The Panel suggests, however, that statements be included to inform statisticians, who are likely to get involved, that many of the terms used are not directly translatable to corresponding statistical parameters or concepts with which statisticians may be more familiar.

5.3 Detailed Comments on Technical Content of Chapter 19

5.3.1 Statistical Approximations of Uncertainty

The Manual needs to clarify its use of statistical approximations. The discussion of uncertainty propagation in subsections 19.5.3 (Combined Standard Uncertainty), 19.5.5.1 (uncertainty propagation for nonlinear models), and 19.5.5.2 (Bias) is incomplete and potentially misleading. In particular, the methods presented are only approximate but this caveat is not always clearly stated. For example, Equation 19.11 on page 19-33, for combined standard uncertainty, is only an approximation, not equality. However, the presentation does not clearly stress the approximate nature of the formula, nor does it indicate the conditions under which this approximation would be valid. Both the use of an equal sign in the equation as well as the use of terminology such as "the uncertainty propagation formula" or the "law of propagation of uncertainty" give the impression that the relationship in Equation 19.11 is equality rather than an approximation.

In general, it would be helpful if the terminology and notation throughout Chapter 19 clearly indicated the approximate nature of most calculations. For instance, Table 19.1 shows all results as equalities, even though most formulas in the table are only approximate (except those for sums and differences). By contrast, in the last row, the table uses an "approximately equal" sign to indicate that $(\ln 10)^2$ is only *approximately* equal to 5.302. This latter result is at least accurate to four significant figures, while in some cases, the results presented as equalities might not be accurate to even a *single* significant figure.

Similar problems appear throughout Chapter 19. Admittedly, when uncertainties are small, the errors associated with the first-order Taylor polynomial are likely to be small. However, the Manual should clearly state whether a formula is an approximation when it is first introduced, and misleading notation and terminology should be avoided.

Section 19.5.5.2 is described as a discussion of bias. However, this section does not seem to use the term in the usual statistical sense, as discussed on pages 19-5 and 19-6, but rather refers

to the potential inaccuracy of the Taylor polynomial approximation. Instead of providing an estimate of the error from use of the Taylor polynomial, the Panel suggests a qualitative discussion of situations in which this approximation is not accurate (e.g., when the uncertainties span a range sufficiently large that the function of interest is not approximately linear over that range).

The discussion in Attachment 19D, "Low-Background Detection Limits," should be revised to explain when someone should consider formulas A, B, and C, the Stapleton approximation, or the exact test. If MARLAP intends to suggest a preferred method, it should be clearly stated, along with recommendations for situations when one of the other methods is preferable.

The Manual should incorporate discussion on the use of Monte Carlo analysis as an alternative means for estimating total uncertainties, such as in the situation mentioned above when the Taylor polynomial approximation would be inaccurate. Section 19.5.5.1 shows how to include higher-order terms in the uncertainty propagation formula. However, the version of the uncertainty propagation formula presented in this subsection assumes that "all the input estimates x_i are uncorrelated," and no mention is made of Monte Carlo simulation as an alternative to the uncertainty propagation formula when uncertainties are substantial. The Panel believes that when uncertainties are large and it is important to have a good estimate of their magnitude, Monte Carlo analysis is generally preferable to the use of Taylor series approximations. Even a second-order Taylor polynomial can be inaccurate when uncertainties are large and the function of interest is significantly nonlinear. Monte Carlo simulation does not have this drawback and can achieve any desired level of accuracy simply by increasing the number of realizations. The Manual should note this and provide one or more references. Comprehensive references on Monte Carlo simulation include Simulation and the Monte Carlo Method (Rubinstein, 1981) and Monte Carlo: Concepts, Algorithms, and Applications (Fishman, 1996). Briefer summaries are given in Uncertainty: A Guide to Dealing With Uncertainty in Quantitative Risk and Policy Analysis (Morgan and Henrion, 1990) and *Statistical Models in Engineering* (Hahn et al., 1994).

5.3.2 Treatment of Negative Analytical Values

The treatment of laboratory data in Chapter 19 could benefit from a better distinction of "à priori" and "à posteriori" data analysis. In the case of "à priori"data, to which Chapter 19 is devoted, the Panel agrees with the recommendation on page 19-13 that laboratories should report negative values when they are obtained, even though such values are physically impossible. It is clear that the measurement process itself can create negative values, even though the physical process cannot. Analytical measurement errors are ubiquitous and caused by random and systematic effects, as well as spurious errors. Whereas random errors are inevitable, and spurious errors (e.g., operator errors) can be generally avoided by good laboratory practices, systematic errors can vary greatly between laboratories. For example, systematic errors that result from defining a mathematical model for the relationship between the measurands and the measurable input quantities on which their values depend, can have significant effects on the measurement process. Input quantities such as instrument background corrections can be optimized for a suite of analyses, but can still lead to systematic measurement errors and mathematically negative

values for the measurand because instruments typically show a positive reading even for samples that are known to contain none of the element of interest. The positive background reading occurs for many reasons, including but not limited to interfering excitation energies, external radiation, instrument noise, or other problems, as discussed in MARLAP. In the case of radionuclides, an additional complication is associated with the presence of background radiation in the sample (e.g., naturally occurring radiation), a topic which is addressed in MARSSIM and other risk management documents. Therefore, even after instrument background has been subtracted out, a set of samples all having zero actual concentration will be represented analytically, in the vicinity of the detection limit, as a distribution of values, about half of which will be negative. Large negative values and/or departures from an equal distribution of negative and positive values can therefore be useful in that they are indicative of the adequacy and quality of the background correction methodology chosen by the operator. In other words, the negative values for the measurand are in part a measure of the suitability and limitations associated with the background correction technique adopted, even though the negative number is not "physically" real.

For these reasons, the Panel supports the recommendation in MARLAP that negative analytical results be reported for any and all "à priori" analytical laboratory results, and that the associated uncertainties always be included, as is the case for any measured value reported. These data need to be readily available for future reexamination, QA review, and numerical manipulations such as averaging, trending, and isopleth plotting. In addition, the Panel recommends that MARLAP authors consider extending the Manual's guidance on the reporting of negative values and values that fall within the measured uncertainty limits, by suggesting that (1) these results should be accompanied by the initials "n.d." to indicate a "nondetect," and (2) further explicatory information should be provided for negative values, such as in footnotes, because reporting of physically impossible negative values may be confusing to nontechnical audiences.

Conversely, in the case of the "à posteriori" use of analytical data, the Panel advises that the application of Bayesian statistical methods be envisioned by MARLAP and documented in future renditions of this report (Borak, 2000; Miller et al., 2000). It may be too early to judge the extent to which a Bayesian approach may be beneficial because of the paucity of peer-reviewed publications on Bayesian analysis of radioanalytical data. However, it appears to be a promising area of research, particularly for cases in which sources of uncertainty are not initially recognized and cannot therefore be quantified using the material based on assumptions about "à priori" distributions as presented in Chapter 19. One recent example involved data generated by a whole-body bremsstrahlung counter that was used for decades (Kozheurov et al., 2002). This counter was subject to a variety of unanticipated influences, such as varying absorption of radon by different types of cloth, seasonally dependent values of radon contamination, and cesium-137 in global fallout. These various sources of uncertainty were recognized only after the collection of an extensive set of "à priori" data. Thus, it was more realistic to reëvaluate the uncertainties in the data on the basis of "à posteriori" data analysis, rather than by using the existing "à priori" uncertainty distribution assumptions.

5.3.3 Use of Examples

Much of the material presented in Chapter 19 is at the limit or beyond the comprehension of laboratory personnel, managers, and planners. Although the material is generally technically sound, it is often too complex and presented with so much mathematical content that the targeted user will have much difficulty in trying to implement the estimation procedures. While the MARLAP Work Group may be reluctant to provide a "cookbook" approach to every procedure, an ordered set of steps in producing each estimate should be given. After each estimation procedure is outlined, it should be followed by a numerical example in which each step is worked out with data values typical of radiological assays. The temptation to make the examples too simple should be avoided. For example, in Attachment 19E "Example Calculation," the uncertainties for each input parameter are provided in the calculation of the combined uncertainty when it is doubtful that most laboratories would have already obtained all of these values. On the other hand, examples should not include factors that are unlikely to occur or have negligible effect. For example, is it necessary to include the effects of buoyancy during weighing and other errors associated with pipettes?

Another potential problem with the current examples is that they seem to imply that the combined uncertainties associated with radiological measurements are small, particularly when compared to uncertainties often encountered in field sampling. For example, the total combined standard uncertainty in Example 19E is only about 14% of the estimated measurand. Perhaps such a small uncertainty is typical of radiological measurements, but the Panel suspects that there may be considerably larger combined uncertainties. Examples of scenarios where one source of uncertainty may dominate and how this situation should be handled would be useful.

6. RESPONSE TO CHARGE QUESTION #4: OVERALL INTEGRATION AND IMPLEMENTATION ISSUES

<u>Charge Question #4:</u> What are the overall integration and implementation issues?

6.1 Integration Issues

Careful reading of the MARLAP Manual reveals considerable attention to integrating it with the earlier MARSSIM document (MARSSIM, 2000). However, it might be useful to devote a short section early in the Manual showing how the whole process is integrated for decisions regarding the cleanup of radioactively contaminated sites. Although the Panel recognizes that MARLAP is not limited to site cleanup decisions, they are probably the most important drivers for creating MARLAP. The proposed new section should also elucidate the areas of overlap between MARLAP and MARSSIM as well as their differences in scope and coverage. The addition of a table summarizing this comparison and linkage is a possible vehicle for this purpose (e.g., see Table 3 at the end of Section 6 as an example).

What is the relationship of MARLAP to other analytical planning guidance issued or required by federal agencies? Primary sources of radiochemical methods for several of the authoring organizations are listed in Table 4 at the end of Section 6. It may be useful to include an appendix in MARLAP that lists "source methods" for specific radionuclide methods, including brief descriptions of the contents of each document, similar to the compilation and description of available guidance on sampling methods in Appendix M of MARSSIM (2000).

Unfortunately, few of the method resources listed in Table 4 fully reflect the proposed MARLAP guidance. However, many of the authoring organizations for the methods are also participants in writing MARLAP. Therefore, these same organizations are well-positioned to revise these methods in a timely fashion following the finalization of MARLAP. The issue is not so much that existing guidance specifies methods incompatible with MARLAP as it is that existing guidance may be too prescriptive about procedures. Without the freedom to use the graded, performance-based MARLAP approach, laboratories may be inhibited from finding the most cost-effective methods for providing the data needed for a decision. Unless the existing guidance is revised to encourage the MARLAP approach, the radiochemistry community will not be able to enjoy all the benefits that MARLAP offers. [Note: The list in Table 4 is based principally on the public comments of Mr. Donivan Porterfield, augmented and reorganized slightly by the Panel. Its completeness and accuracy have not been assessed by the Panel, which offers it simply as a starting point for an effort by the MARLAP Work Group to respond to the Panel's recommendation.]

The Panel believes that it would be useful to show, perhaps through a table of connections, how the MARLAP Manual interfaces with, augments, or replaces existing guidance on radiochemical analyses. Where existing guidance appears to limit the impact of MARLAP, or even conflict with it, perhaps the source agency should be encouraged to amend it or even officially withdraw it in favor of MARLAP. MARLAP may wish to recommend that those participating agencies that currently attempt to control the quality of analysis by specifying

methods, as in the regulations for the Safe Drinking Water Act, use MARLAP to control by protocol instead of method, and leave method selection to the analyst. The Panel encourages each of the authoring organizations to initiate a review of its existing guidance and to withdraw or revise them if necessary to reflect the MARLAP guidance. Otherwise, a mixed message will be sent to the user community: on the one hand, advocating the right way to do radiochemical analyses, while on the other hand likely legally requiring the usage of radiochemical methods that follow outdated practices.

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The documents listed in Table 4 provide a good start as references for well-established and widely-accepted analytical procedures that have been developed over the past 50 years for various radionuclides. The Panel suggests that the federal MARLAP Work Group consider including this information in the Manual, and that it expand the list to include other sources of information and references that could assist users in searching and locating individual radiochemical procedures. Some examples of such resources are (1) the Nuclear Sciences Series of monograms on individual radioelements, that is published by the National Academy of Sciences series of monograms, (2) specific journal articles in Analytical Chemistry, Health Physics, Radioactivity and Radiochemistry, Radioanalytical and Nuclear Chemistry, and Chemical Abstracts, and (3) specific specialized books, reports, manuals and symposium proceedings of interest to radioanalytical chemists. Although MARLAP advocates a performance-based approach to analyses and is not intended to be a "cookbook" of analytical "recipes," users nonetheless will need to seek specific laboratory procedures that could best meet the given requirements of a project. If such a list were to be provided in the Manual, then a simple disclaimer may be included with it, stating that the various participating organizations consider the listed documents to be valuable information sources on specific radiochemical procedures (without sanctioning any specific method).

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6.2 Implementation Issues

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Composition of the Planning Team

1865 Section 2.4 in MARLAP discusses the composition of the planning team. The first 1866 paragraph of that section states "MARLAP recommends that the planning team consist of all of the 1867 parties who have a vested interest in, or who can influence, the outcome (stakeholders)." In the 1868 following paragraph, the Manual presents a list of potential representatives that does not 1869 explicitly include the parties paying for the analyses and potentially for remedial actions 1870 afterwards (e.g., the Potentially Responsible Parties for a Superfund site). This disconnect may or 1871 may not have been intentional; the Panel can think of reasons for including and for excluding that 1872 class of stakeholders, likely depending on the specific decision for which the analyses are being 1873 conducted. The Panel strongly recommends that the issue be discussed in Section 2.4 and, if 1874 there is consensus among the federal MARLAP Work Group, the MARLAP recommendation be 1875 made clear. In some cases, moreover, it may be appropriate to include representatives from the

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6.2.2 Availability of a Trained Workforce

candidate performing laboratory(ies).

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The MARLAP Manual recommends that planning teams include "radioanalytical specialists." Because any individual will rarely have substantial expertise in all the areas of

interest to radioanalysis (e.g., wet chemistry, spectrometry, statistics, QA/QC), the teams may need either to include several such individuals or to recruit an individual with general knowledge of radioanalytical issues AND specially trained in the MARLAP process. In doing so, the widespread use of MARLAP may create a demand for such individuals that substantially exceeds the current supply. Declining interest in nuclear power and less emphasis on nuclear weapons as the centerpiece of U.S. national security has allowed the pool of radioanalytic specialists to diminish. The MARLAP agencies may need to stimulate a new generation of such experts through scholarship programs or other means in order to implement MARLAP as envisioned.

6.2.3

6.2.3 User Training

Although the planning process is straightforward and logical, the learning curve is steep at first. Well-designed training courses would be an efficient approach to get new users comfortable with the process more quickly. In designing these courses, the Panel recommends that the federal MARLAP Work Group meet with the federal MARSSIM Work Group to find out the lessons learned by this team over the last couple years. For example, how has MARSSIM dealt with the highly variable starting points of prior experience and expertise among the course attendees? MARLAP is more likely to succeed if separate training courses are tailored for different audiences: managers, radioanalytical specialists, laboratory personnel, perhaps auditors. However, it will also be important for the courses to overlap at least slightly in coverage so as to enhance communication among user groups by ensuring that participants speak a common language and that all see how each fits into the "big picture." The federal MARLAP Work Group could also consider offering or coordinating some of the MARLAP training through the National Environmental Laboratory Accreditation Conference (NELAC). The stated purpose of this voluntary association of State and Federal agencies, which first convened in 1995, is to establish and promote performance standards for environmental laboratory operations (EPA, 2002). NELAC provides a well-established forum for the private sector to interact with, and provide input to, regulatory agencies in the environmental arena.

Moreover, it is important to take advantage of user feedback not only on the effectiveness of training but also on MARLAP itself. Users may be able to identify requirements in MARLAP that are infeasible or counterproductive or, by contrast, identify additions to MARLAP that would result in data products better suited to the needs of specific decisions. MARLAP could then become a dynamic document that could respond to users' comments in future revisions. The MARLAP web site could serve as one place to receive suggestions for improvement, for example by offering a bulletin board. The Panel recommends that the authoring agencies commit to the implementation of training and outreach programs with the goal of achieving better use of the current version of MARLAP and improvements in future versions.

The Panel also recommends that role-playing exercises be part of the user training courses. The Panel subcommittee addressing the overall approach, i.e., responding to Charge Question #1, employed this tool at its April 24, 2002 work session. In order to get a sense of how a laboratory manager or other critical users might perceive MARLAP, the Subcommittee engaged in a role-playing exercise with members of the federal MARLAP Work Group. The scenario that was posed was based on a real situation in which elevated alpha activity had been detected in an unofficial groundwater sample collected from one of the monitoring wells adjacent to a privately-

owned landfill. Subcommittee members took on the roles of the county administrator, landfill owner, a representative of the State environmental regulatory agency, and a concerned citizen from the neighborhood adjacent to the landfill. The federal MARLAP Work Group members adopted the roles of various types of "radioanalytical specialists" that included an analytical laboratory manager, an independent advisor for the county, and legal advisor to the landfill owner. The assignment to this group was to work through the MARLAP planning process described in Part I of the Manual. The radiochemical specialists were asked to direct the Panel members to the appropriate pages in the Manual that best described each step of the process.

The exercise only lasted a half hour, during which time the group was able to come to consensus on the problem definition, decision identification, data inputs, and decision boundaries. Due to lack of time, the exercise did not proceed as far as developing decision rules, specifying limits on decision error rates, or developing DQOs, MQOs, APSs, or a SOW. Nonetheless, this cooperative exercise was invaluable for focusing attention of the group upon relevant advice provided in MARLAP. It not only facilitated the flow of information from the federal MARLAP Work Group to the Subcommittee, but also provided an opportunity for the Work Group to hear and understand the concerns of the Subcommittee, particularly in identifying areas where MARLAP guidance may be confusing, scattered, or not a practical guide for the user. Participants gained an appreciation for the critical importance of the appendices for key information needed to work through the planning process. Subcommittee members also became more cognizant of the very nonlinear and iterative nature of the planning process, even starting at its first step. The exercise raised the awareness of the MARLAP Work Group with respect to several training issues: how to conduct training, what to include in it, how important it will be, and assumptions about the prior level of knowledge of the user community. All participants appreciated the highly variable "starting points" of prior experience and expertise, and recognized the challenge of designing training that takes this variability into account. The consensus was that scenarios and training will be critical to the success of MARLAP, by illustrating the planning process, driving home the potential benefits of the process, and "bringing it to life."

Finally, user training may be enhanced through the provision of workbooks allowing trainees to work through example exercises illustrating the various major tasks of MARLAP. These examples should be neither so simple as to hide the true complexities of implementing a laboratory project within the MARLAP guidance nor so complicated that judging the adequacy of the trainee's answers would be difficult. These workbooks would not strictly be a part of the MARLAP Manual but could be considered appendages useful in training or available for reference prior to undertaking an unfamiliar type of project.

6.3 Future Enhancements of MARLAP

Many of the changes recommended by the Panel could require considerable effort to implement in full, and it is not the Panel's intent that release of the Manual be held up to do so. The value of the Manual to the user community will best be realized if it is managed as a "living document" with a mechanism in place for its ongoing maintenance and continual improvement as a multi-agency consensus product. The essence of the MARLAP Manual is to promote a flexible approach that permits a wide range of analytical procedures, from which a few are selected to meet the specific needs of a project. It is likely that different procedures will be developed to

meet different DQOs, with a secondary objective of minimizing the cost of analysis. Additional analytical techniques will be developed for a variety of analytical needs, including speciation of the radionuclides of interest. Hence, a mechanism should be developed to promote the exchange of analytical procedures among laboratory personnel, perhaps using MARLAP user groups to instigate, facilitate, and document the results of such exchanges.

The following list reiterates some of the longer-term enhancements envisioned by the Panel for the Manual, as described elsewhere in this report:

1. Better integration with MARSSIM guidance on developing and implementing sampling and analysis plans,

2. Guidance on the use of Monte Carlo approaches to estimate uncertainties,

Guidance on the application of Bayesian analysis to à posteriori data,
 Up-to-date and indexed list of method resources that describe advances in sampling, separation, and analytical techniques for radionuclides, including speciation and oxidation states in the environment,

 5. Up-to-date list of relevant regulations and other documents issued by regulatory agencies, including web-site addresses,

6. Development of companion workbooks for target audiences,

 7. Development of appendices containing examples of good planning, implementing, and reporting documents,

 8. Development of a simpler version of MARLAP geared for the planning and implementation of small projects,
9. Development of a computerized version of MARLAP that includes hyperlinks for

navigation, and
Development of updated scenarios and examples that reflect the real-world experiences of users.

Issue	MARLAP	MARSSIM
Performance-based approach	Underlying basis and recurring theme throughout Part 1, involving 3 major steps: planning, implementation, and assessment. (Section 1.4.3)	Uses the data life cycle as the basis its performance-based approach, bu does not explicitly define this term
Directed planning process	Briefly describes several directed planning processes suitable for projects requiring the collection of radioanalytical data, and presents the DQO process in detail (Chapter 2, Appendix A); detailed discussion of role of radioanalytical specialist in this process (Section 2.5)	Uses the DQO process (which is or type of directed planning process) (Section 2.3.1, Appendix D)
Graded approach	Recommends the use of a graded approach (Section 2.3.1), and discusses its application to planning (Sections 4.3 and 4.5.3) and data assessment (Section 9.3)	Emphasizes the use of a graded approach for sampling contaminate areas (Section 2.2, 2.3) and provide example of a graded approach (Appendix B)
Data life cycle	Defines three phases: planning, implementation, assessment (Section 1.4.1)	Defines four phases: planning, implementation, assessment, makir decision (Section 2.3, Appendix D, Appendix E)
Data Quality Objective (DQO) process	Defines 4 elements for this directed planning process in Section 2.3.3; 7 steps described in detail in Appendix B.	Defines 7 steps in the DQO process (Section 2.3.1, Appendix D)
Data verification and validation	Extensive discussion of the verification and validation process (Chapter 8)	Very brief discussions in Section 9 Provides example of data validation using 6 data descriptors (Appendix
Data Quality Assessment (DQA) process	Defines 4 steps in the DQA process: review project plan document (including DQOs), assess whether samples are representative, assess data accuracy, assess whether decision can be made (Section 9.6)	Defines 5 steps in the DQA process review DQOs and survey design, conduct preliminary data review, so statistical test, verify test assumption draw conclusions (Section 2.3.3, 8. Appendix E)
Sampling design	Sampling design is outside scope	Extensive discussion of survey planning and design (Chapters 4-5)
Field sampling	Extensive discussion of field sampling, focusing on those issues that affect laboratory measurements, such as sample size, containers, filtering, preservation, storage, and transport (Chapter 10)	Extensive discussion of field sample protocols, mostly focusing on field surveys (Chapter 6), but also include sampling for laboratory measurement (Chapter 7). Provides list of source sampling methods (Appendix M)
Radiation field equipment and measurement protocols	Brief discussion of field measurements from perspective of how conditions under which these measurements are obtained differ from those in a laboratory (Attachment 15A)	1-2 page descriptions of common to of field survey equipment (Append H.2) Equipment summary tables organize by type of radiation to be surveyed (Tables H.1 to H.5) Brief discussions on measurement protocols (Chapter 6)
Radon field measurements	Brief overviews of radon sampling methods (Section 10.5.5)	Extensive discussion of radon measurement methods (Section 6.9 Appendix H.2.4, Table H.4)

Issue	MARLAP	MARSSIM
Radiation laboratory equipment and measurement protocols	Major focus of Part 2, which covers sample preparation, dissolution and separation techniques, instrumentation, calibration, and data acquisition in depth (Chapters 12 to 17)	1-2 page descriptions of common types of laboratory instrumentation (Appendix H.3), Equipment summary table of systems that measure atomic mass or emissions (Table H.5)
Obtaining and evaluating laboratory services	Selecting and evaluating laboratories are covered in depth, including contractual specifications (Chapters 5 and 7; Appendix E)	Laboratory selection is briefly reviewed (Section 7.4); evaluation of laboratory services is outside scope
Action level	Discusses use of generic "action level" to formulate and test hypothesis about contamination (Appendix C)	Defines action level as the derived concentration guideline level (DCGL), which is used to formulate and test hypothesis about contamination (Sections 2.2 and 4.3)
Statistical tests for data evaluation	Detailed discussion of statistical tests suitable for testing hypotheses about contaminant (Chapter 19 and its attachments, Appendix C). Provides statistical tables (Appendix G)	Describes tests suitable for use depending upon whether the contaminant is absent or present in the background (Chapter 8, Appendix E). Provides statistical tables and brief descriptions of specific statistical procedures (Appendix I)
QA/QC for measurements	Discusses performance indicators for radiochemical and instrumentation steps of radioanalytical procedures (Chapter 18)	Brief discussion of quality assurance project plan (QAPP) and data assessment procedures (Chapter 9); discusses use of Data Quality Indicators (DQI) (Section N.6)
Decision rules and decision errors	Extensively discussed (Appendix B)	Extensively discussed (Appendix D.5 and D.6)
Reporting data	Stresses importance of reporting actual data, including negative values. Data reports should include appropriate number of significant figures, and combined or expanded uncertainties (Section 19.3.9).	Stresses importance of reporting actual data, including negative values and results with large uncertainties. Data reports should include appropriate number of significant figures, uncertainties, and applicable method detection limit (MDL). Recommends reporting results in same units as DCGL. (Section 2.3.5)
Laboratory or field health and safety	Briefly mentioned, but no extensive discussions (Sections 10.2.11 and 14.10.9)	Briefly mentioned
Laboratory waste management	Discussed in very general terms in Chapter 20	Not discussed
Regulations requiring radioanalytical data	Outside scope	Summarizes applicable regulations (Appendix C). Describes relationship of MARSSIM to CERCLA and RCRA Corrective Action process (Appendix F)

Table 4. Analytical Planning Guidance Issued or Used by Agencies and Organizations Authoring MARLAP*

U.S. Environmental Protection Agency

EPA (1976) Interim Radiochemical Methodology for Drinking Water, EPA 600/4–75–008 (revised), March 1976.

 EPA (1979) Radiochemical Analytical Procedures for Analysis of Environmental Samples, March 1979.

EPA (1980) Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA 600/4–80–032. August 1980.

EPA (1987) Radiochemistry Procedures Manual, EPA 520/5-84-006, December 1987.

EPA (1997) Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-B-97-001, March 1997.

40 CFR 61 National Emission Standards for Hazardous Air Pollutants, Part B radiochemical methods.

U.S. Geological Survey

USGS (1976) Selected Methods of the U.S. Geological Survey of Analysis of Wastewaters, Open-File Report 76–177.

USGS (1977) "Methods for Determination of Radioactive Substances in Water and Fluvial Sediments", Chapter A5 in Book 5, Techniques of Water-Resources Investigations of the United States Geological Survey.

U.S. Department of Energy

DOE (1982) RESL Analytical Chemistry Branch Procedures Manual, IDO-12096, U.S. Department of Energy, Idaho Falls. ID.

DOE (1990) *EML Procedures Manual*, 27th Edition, Volume 1, HASL-300. Environmental Measurements Laboratory, New York, NY. [N.B.: As of September 2002, this reference is no longer available in hard copy but is available on CD and on the internet at: http://www.eml.doe.gov/publications/procman.cfm]

DOE (no date) Methods for Evaluating Environmental and Waste Management Samples.

States:

State of New York (1982) *Determination of Ra-226 and Ra-228 (Ra-02)*, January 1980, Revised June 1982. Radiological Institute Center for Research, New York State Department of Health, Albany, NY.

State of New Jersey (1980) *Determination of Radium 228 in Drinking Water*, August 1980. New Jersey Department of Environmental Protection, Division of Environmental Quality, Bureau of Radiation and Inorganic Analytical Services, Trenton, NJ.

American Society for Testing and Materials (ASTM) International:

ASTM (1994) *Annual Book of ASTM Standards*, Vol. 11.02. American Society for Testing and Materials, West Conshohocken, PA.

American Public Health Assocation (APHA)

APHA (1971, 1989, 1992, 1995) Standard Methods for the Examination of Water and Wastewater, 13th edition

2101 2102 2103	(1971), 17 th edition (1989), 18 th edition (1992), and 19th Edition (1995). American Public Health Association, Washington, D.C.
2104 2105 2106	* Based on a list provided by Mr. Donivan Porterfield, and amended by the Panel. Most of these documents are referenced on the EPA website at http://www.epa.gov/safewater/methods/rads.html

^{*} Based on a list provided by Mr. Donivan Porterfield, and amended by the Panel. Most of these documents are referenced on the EPA website at http://www.epa.gov/safewater/methods/rads.html

7. SUMMARY OF FINDINGS AND RECOMMENDATIONS

7.1 Overall

The MARLAP Manual is comprehensive and provides answers--or citations to documents with answers--to virtually all of the questions that might be asked about radiochemical analyses in support of environmental decisions. Moreover, its graded and flexible approach allows a user to select a set of analytical procedures suited to the complexity and importance of the problem being addressed. The Manual in general provides a convincing rationale for its recommendations, showing how decisions can be supported with sufficient but not excessive attention to analytical precision and reliability. It does a thorough job of explaining how decision makers should make choices in the selection of hypotheses that help determine the confidence levels associated with the results obtained from analytical laboratories.

One of the major drawbacks of the draft MARLAP document is the sheer size of its two volumes. Furthermore, the individual volumes are not self-contained because all appendices have been relegated to the back of the second volume. The Panel suggests that a more efficient goal would be to reorganize Part I to include Appendices A to E, and to consider dividing Part II into two parts to facilitate convenient use in the laboratory. A reasonable separation may be between Chapters 10 to 14 (with Appendix F), which focuses on radiochemistry, and Chapters 15 to 20 (with Appendix G), which focuses on radiation detection and quantification.

7.2 Charge Question #1: Effectiveness and Clarity of the Overall Approach in Part I

7.2.1 Comments

- 1. The performance-based and flexible approach in MARLAP is appropriate and, for the most part, presented clearly and logically in the draft MARLAP Manual.
- 2. The guidance provided with regard to a graded approach for projects of different scope, as well as the emphasis on data quality sufficient for the decision being supported, is reasonable.
- 3. The linkage of the planning, implementation, and assessment phases of projects involving radioanalytical data is effective.

7.2.2 Recommendations

The following recommendations are listed in order of the priority placed on them by the Panel.

1. The Manual should undergo a thorough technical edit, the main objectives of which should be to (a) remove the considerable amount of redundancy, (b) ensure internal consistency among the chapters in presentation style and formatting, (c) make wider and more consistent use of effective techniques for presenting information, (d) proofread all references, equations, tables, figures, and examples, and (e) reduce the use of acronyms.

- 2. Provide a well-written Executive Summary using clear, simple text, and figures to unify the document and show the linkages among the chapters.

 2. Provide a well-written Executive Summary using clear, simple text, and figures to unify the document and show the linkages among the chapters.
- 3. A good overview figure is needed at the outset, a figure that lays out the entire planning process and shows the interrelationships among the steps.
 - 4. More examples should be included in the Manual to illustrate the planning process and the graded approach, so as to bring these to life for the reader. A variety of clearly presented and realistic scenarios will be critical to the success of MARLAP and should emphasize the potential benefits of planning and using a graded approach.
 - 5. To address the concern that regulatory agencies may try to apply the entire MARLAP process to situations and organizations for which a full-scale effort would not be appropriate, the Panel suggests the inclusion of more explicit guidance on how to scale back the process to a level appropriate to the decision under consideration.
 - 6. Figures and tables should be designed so as to reinforce the text, or to help reduce the need for lengthy discussions. In particular, the very nonlinear and iterative nature of the planning process should be indicated by feedback loops in figures to more clearly convey the sense of the process of continual reassessing and fine-tuning the objectives and approaches.
 - 7. An appendix containing good examples of process outputs (e.g., DQOs and Statements of Work) for projects differing in scope and complexity would be helpful.

7.3 Charge Question #2: Technical Accuracy of the Guidance in Part II

7.3.1 Comments

- 1. Subject to caveats listed in this review, Part II of the MARLAP document provides a much needed resource base for laboratory operations, and its guidance, on the whole, is reliable and well thought out.
- 2. Numerous technical inaccuracies and inconsistencies in the Manual are identified, as well as incomplete compilation of sampling methods or sampling data needs and additional complexities associated with specific analytical methods and techniques. These detailed comments are listed in Appendix C.
- 3. Some of the main issues with MARLAP do not concern the content but the ease of its use as a practical tool. The implementation of radiochemical analyses is often driven by the requirements of existing methods set as standards by different organizations. Until these methods are revised, and commitments from the authoring organizations are obtained, the radiochemistry community may be in conflict over the application of MARLAP guidance.

7.3.2 Recommendations

 As with the recommendations in Section 7.2.2, the following recommendations are given in order of priority.

1. The Panel strongly supports the initiation and maintenance of a teaching program and the implementation of a web site to enhance dissemination of guidance on issues related to MARLAP.

2. Restructuring some of the chapters in Part II could add clarity and usefulness to the document by providing more consistency in the level of detail, employing a more logical order of presentation, and inserting appropriate cross-references between chapters to reduce confusion and repetition. Discussion of limited value should be deleted, with the reader referred to specific publications (e.g., special matrices and radionuclide behavior in the environment).

3. Although the Panel agrees that the laboratory must report values "as measured" when below the limit of detection--or even negative through subtraction of background--presentations of the data annotated with qualitative indicators of non-detectability or less-than notation may be desirable to include in reports to the lay public and to decision makers. The Manual should address this issue and attempt to find a solution that would maximize lay understanding while minimizing the potential for misuse.

4. The federal MARLAP Work Group has provided guidance on laboratory analyses with the intent of ensuring that the uncertainties in their results do not contribute significantly to the overall uncertainty of the decision process, including those from the sampling design and those from translating risk-reduction policy goals to action levels. This intent should be further clarified in the Manual, and the issue of tradeoffs between sampling coverage and laboratory precision should also be discussed.

7.4 Charge Question #3: Guidance on Measurement Statistics

7.4.1 Comments

1. From a technical perspective, statistical issues are addressed very well in the draft MARLAP Manual. From a presentation perspective, however, too much material is included in Chapter 19, the material is not presented in the most logical order, the technical discussions are too complex for the target audience of laboratory directors and staff, and the terminology differs from that most commonly used by statisticians.

7.4.2 Recommendations

The recommendations on statistical issues are presented in the order of importance.

1. Many of the terms used in the measurement statistics chapter may be commonly employed

in the jargon of laboratory science, but these terms are confusing when read by statisticians. Statements should be included to inform statisticians, who are likely to get involved, that many of the terms used are not directly translatable to corresponding statistical parameters or concepts with which statisticians may be more familiar.

- 2. The Panel recommends that the distinctions and connections between uncertainty and variability be discussed early in the section on measurement statistics.
- 3. The terminology and notation throughout Chapter 19 should clearly indicate the approximate nature of most calculations and clearly state whether a formula is an approximation when it is first introduced. It should also indicate the conditions under which each approximation would or would not be valid. If MARLAP intends to suggest a preferred method, it should be clearly stated, along with recommendations for situations when one of the other methods is preferable. For example, Attachment 19D should provide recommendations regarding which of formulae A, B, C, the Stapleton approximation, or the exact test are preferred and under what conditions.
- 4. The Manual should incorporate discussion on the use of Monte Carlo analysis as an alternative means for estimating total uncertainties. Given recent advances in desktop computers and work stations, computational restrictions on the use of Monte Carlo methods are no longer a concern. In this case, however, the user needs to be reminded that assumptions about parameter distributions are critical.
- 5. The steps used for each statistical estimate should be clearly laid out in chronological order so that users of MARLAP will know how to begin and how to progress through the estimation process. After each estimation procedure is outlined, it should be followed by a numerical example in which each step is worked out with data values typical of radiological assays.
- 6. The potential use of Bayesian analysis should be explored, particularly as a way to address the problem of negative values resulting from background-corrected laboratory data.
- 7. The current statistical examples seem to imply that the combined uncertainties associated with radiological measurements are small, particularly when compared to uncertainties often encountered in field sampling. Examples of scenarios where one source of uncertainty may dominate and how this situation should be handled would be useful.

7.5 Charge Question #4: Overall Integration and Implementation Issues

The following recommendations are given in priority order:

1. The Panel believes that scenarios and training will be critical to the success of MARLAP, by illustrating the planning process, driving home the potential benefits of the process, and "bringing it to life" for the user community. The Panel recommends that role-playing exercises be part of the user training courses.

2290 2. The Panel recommends that the MARLAP Work Group meet with the MARSSIM Work
2291 Group to find out the lessons learned by this team over the last couple years for
2292 developing well-designed training courses.

- 3. The Panel recommends that the MARLAP Work Group take advantage of the training sessions to obtain user feedback not only on the effectiveness of training but also on MARLAP itself. Users may be able to identify requirements in MARLAP that are infeasible or counterproductive or, by contrast, identify additions to MARLAP that would result in data products better suited to the needs of specific decisions.
 - 4. It might be useful to devote a short section early in the Manual to showing how the MARSSIM and MARLAP processes are integrated for decisions regarding the cleanup of radioactively contaminated sites.
 - 5. It would be useful to show, perhaps through a table of connections, how the MARLAP Manual interfaces with, augments, or replaces existing guidance on radiochemical analyses.
- 6. Although it is outside the scope of the Panel's charge, the Panel recommends that each of the authoring organizations seek to establish a time frame for reviewing and revising the radiochemical method resources issued by their organizations to fully reflect the MARLAP guidance. Otherwise, a mixed message will be sent to the user community: on the one hand, advocating the right way to do radiochemical analyses, while on the other hand likely legally requiring the usage of radiochemical methods that follow outdated practices.

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2433 APPENDIX A DETAILED DESCRIPTION OF THE SAB PROCESS AND ITS CHARGE 2434 2435 The EPA Office of Radiation and Indoor Air (ORIA) requested that the Radiation 2436 Advisory Committee (RAC) of the Science Advisory Board (SAB) review the Multi-Agency 2437 Radiological Laboratory Protocols Manual (MARLAP). The MARLAP was introduced to the 2438 RAC at its August 1, 2000 meeting in Washington, DC. The Manual was still in early draft form 2439 at that time and was not available for the RAC to study, beyond the Table of Contents. 2440 The SAB Staff recruited Dr. Jan Johnson, Executive Committee Member of the SAB and 2441 Chair of the SAB RAC, to serve as Chair of the MARLAP Review Panel. The RAC determined 2442 that additional expertise would be needed for the review to assist in addressing the accuracy of its 2443 radiochemical and statistical guidance. Working with the Chair, other SAB members and consultants, Agency Staff, and suggestions from the public, the SAB Staff identified scientists 2444 2445 and engineers ("Wide Cast") whose expertise appeared to be relevant to answering the questions 2446 in the Charge. Subsequently, the Chair, the Staff Director, and the Designated Federal Official 2447 (DFO) reviewed the list in some detail and identified individuals ("Narrow Cast") to contact 2448 regarding their interest and availability to participate on the Panel. Based on this information and 2449 the importance of having a balanced range of views on the technical issues represented on the 2450 Panel, the Chair and the DFO made recommendations for membership to the Staff Director, who 2451 made the final decision on the composition of the Panel. This process included assigning Lead 2452 and Associate responsibilities to specific Panel members for each of the Charge questions. 2453 The draft Manual was made available to the MARLAP Review Panel in September 2001. 2454 The Panel completed its review in November 2002. This Appendix describes the details of the 2455 Panel's review schedule and process. 2456 **A.1 Charge Questions and Subcommittee Assignments** 2457 Members of the MARLAP Review Panel addressed the specific charge questions posed by ORIA by organizing into subcommittees for each question, and allocating specific chapters and 2458 2459 appendices to each subcommittee. 2460 Charge Question #1: Is the overall approach presented in Part 1 of MARLAP for the planning, implementation and 2461 2462 assessment phases of projects which require analysis for radionuclides technically acceptable? 2463 *1a. Is the performance-based approach presented clearly and logically?* 2464 *1b. Is the approach reasonable in terms of ease of implementation?* 2465 1c. Does the approach effectively link the three phases (planning, implementation, assessment) of 2466 a project?

2468	Subcommittee chair: Dr. June Fabryka-Martin
2469	Subcommittee members: Dr. Steve Brown, Dr. Bruce Boecker, Dr. Jill Lipoti, Dr. Helen Grogar
2470	Applicable MARLAP chapters:
2471	Primary review materials: Chapters 1-9; Appendices A, B and C
2472	Secondary review materials: Chapters 11 and 18
2473	General review: all chapters and appendices
2474	
2475	Charge Question #2:
2476 2477 2478	Is the guidance on laboratory operations in the Part II chapters technically accurate? Does it provide a useful resource base of information for a laboratory's implementation of a performance-based approach?
2479	
2480	Subcommittee chair: Prof. Bernd Kahn
2481 2482	Subcommittee members: Prof. Tom Gesell, Dr. Gilles Bussod, Prof. Genevieve Roessler ¹ , Prof. Shawki Ibrahim
2483	
2484	Applicable MARLAP chapters:
2485	Primary review materials: Chapters 10-18 and 20
2486	Secondary review materials: Chapters 1, 2, 5, 6 and 8
2487	General review: all chapters and appendices
2488	
2489	Charge Question #3:
2490 2491 2492	Is the guidance on measurement statistics - specifically measurement uncertainty and detection and quantification capability - technically accurate, clearly presented, and useful for implementation by appropriately trained personnel?
2493	
2494	Subcommittee chair: Dr. Richard Hornung
2495 2496	Subcommittee members: Dr. Vicki Bier, Dr. Mike Ginevan, Prof. Lynn Anspaugh, Dr. Bobby Scott

Dr. Genevieve Roessler chaired this activity in the absence of Dr. Kahn at the April 23-25, 2002 meeting. She was assisted by Drs. Bussod, Gesell, and Ibrahim and others as appropriate.

2497 Applicable MARLAP chapters: 2498 Primary review materials: Chapter 19; Appendices B and E; Attachment B-1 2499 Secondary review materials: Chapters 1, 3, 5, 6, 8, 17 and 18.3 2500 General review: all chapters and appendices 2501 2502 Charge Question #4: The MARLAP Review Panel added this fourth charge question during a 2503 planning conference call: 2504 What are the overall integration and implementation issues? 2505 2506 Subcommittee chair: Dr. Steve Brown 2507 Subcommittee members: All MARLAP Review Panel members and consultants 2508 2509 Applicable MARLAP chapters: All materials, and possibly additional supplemental items from 2510 other sources. 2511 2512 **A.2 Panel Review Schedule and Process** 2513 2514 The RAC was introduced to the MARLAP topic at its publicly-accessible Federal Register-2515 noticed planning meeting on August 1, 2000 and a subsequent public planning meeting on 2516 MARLAP and other topics on December 12-14, 2000. At the December 12-14, 2000 RAC 2517 planning meeting, the RAC determined that additional expertise would be needed for the review. 2518 Consequently, several consultants were added to the widecast list as candidates for the MARLAP 2519 Review Panel to assist in addressing the organizational aspects of the Manual, as well as the 2520 accuracy of the radiochemical and statistical guidance contained in the Manual. The RAC's 2521 MARLAP Review Panel held its first formal meeting on MARLAP as a public conference call on 2522 April 8, 2002. The goal of this information-gathering conference call meeting was to clarify any 2523 questions that the MARLAP Review Panelists might have, to identify any gaps in the review 2524 materials and any other information sent to the Panel, and to identify areas that the Agency and 2525 the federal MARLAP Work Group should be prepared to clarify at the face-to-face meeting. The 2526 RAC's MARLAP Review Panel added a fourth charge question during this April 8, 2002 2527 planning conference call dealing with the topic of overall integration and implementation issues. 2528 2529 On April 23 through 25, 2002 the Panel convened a in the EPA Headquarters Building, 2530 EPA East Building Hearing Room 1153, Washington, DC. The federal MARLAP Work Group 2531 participating in this review included technical staff from the following agencies, departments and 2532 commissions: the U.S. Environmental Protection Agency (EPA), Office of Radiation and Indoor 2533 Air (ORIA), the Department of Energy (DOE), the Department of Defense (DoD), the Nuclear 2534 Regulatory Commission (NRC), the National Institute of Standards and Technology (NIST), the 2535 U.S. Geological Survey (USGS), and the U.S. Food and Drug Administration (FDA). State

participation in the development of the Manual involved contributions from representatives from the Commonwealth of Kentucky and the State of California.

During the April 23 - 25, 2002 public meeting, the SAB's MARLAP Review Panel heard presentations from the Agency and the federal MARLAP Work Group staff on the first day. Public comments were received from Mr. Donivan Porterfield in advance of the meeting. No additional public comments were received at this meeting. The presentations were followed by detailed discussion by the MARLAP Panelists on the four charge questions in break-out sessions held in smaller rooms adjacent to or in close proximity to the EPA Hearing Room, in which all participants were invited to participate. The second day saw continued break-out session discussions, a re-convening of the MARLAP Review Panel to discuss its progress and next tasks, and the making of additional writing assignments by the subcommittee chairs. The discussion in the break-out sessions focused on key points within each charge question, as well as re-writing of the pre-meeting written comments by the Panelists to their assigned charge questions, and teaming in groups by the Panelists to develop merged language edits.

By the end of the second day, the individual comments and merged edits were discussed by the Panelists within each of the Working Groups. The third day was engaged with more refinements of the written materials and focused discussions within each of the subcommittees. The MARLAP Review Panel decided to exercise its option to conduct a planned technical editing public conference call in June 27, in which the public can follow the Review Panel's discussions on the working draft, which is not yet a public consensus report. The Review Panel anticipated that a public consensus draft would be completed at the end of August, and planned to hold a second public face-to-face meeting at the end of September to reach closure on edits to that draft report. The first "working" public draft was developed on August 29, 2002 and posted on the SAB web site (www.epa.gov/sab under "draft reports") for discussion at the MARLAP Review Panel's Sept 24-26, 2002 meeting. It is important to note that early on in the process, the MARLAP Review Panel identified the need for two face-to-face public meetings to resolve issues, have extensive discussions, and reach a point where closure could be achieved on this complex and detailed topic.

The MARLAP Review Panel held its planned second public meeting to reach closure on September 24 -26, 2002 in which the first public draft report, dated August 29, 2002 was shared with all parties and on which public comments were solicited on the August 29, 2002 public draft report. Following receipt of Panel and public comments, a revised working draft dated was prepared and the Panel convened a technical editing (non-FACA) work session on to complete the edits. Following work session, the edits were incorporated into a second public draft report dated December 18, 2002. This draft was provided to the SAB's Executive Committee and the MARLAP Review Panel, and was posted on the SAB web site (www.epa.gov/sab under "draft reports") for access by the public (including the Agency). A public closure meeting was held on January 14-15, 2003 in which the SAB's Executive Committee and the public was given an opportunity for closure comments. At the January 14-15, 2002 SAB Executive Committee meeting the public was invited to comment by the Chair of the SAB Executive Committee. The

2579 Chair of the MARLAP Review Panel conferred with the SAB Executive Committee discussants 2580 and completed the edits to this advisory, resulting in this final version being submitted to the 2581 Administrator. 2582 NOTE: Throughout the process, the SAB has provided announcements in the Federal Register, as well as posting notices, agendas, and the publicly-available draft reports on the SAB web site 2583 2584 (www.epa.gov/sab), along with related efforts to reach out to all potentially affected and 2585 interested parties. This also included a public conference call meeting prior to the April, 2002 2586 face-to-face public meeting to discuss and negotiate the charge, determine if the review materials 2587 are adequate, and begin the pre-meeting review and writing process. The MARLAP Work Group 2588 also provided a URL site for the MARLAP Manual and received extensive public comments as 2589 well as comments from all the Agencies, departments and commissions involved, including 2590 review materials, appendices, background briefings and related materials.

2592		APPENDIX B
2593		ACRONYMS AND ABBREVIATIONS
2594		
2595	NOTE: Brac	keted references following each definition represent the location in which the acronym first appears.
2596		
2597	п	probability of making a Type I error, i.e., false positive [Appendix C]
2598	п	alpha particle (type of radiation) [Table 2]
2599	\$	probability of making a Type II error, i.e., false negative [Appendix C]
2600	\$	beta particle (type of radiation) [Table 2]
2601	F	total standard deviation [Appendix C]
2602	F_s	standard deviation of the sampled population [Appendix C]
2603	: m	micrometer [Section 4]
2604	ACE	U.S. Army Corps of Engineers [Appendix C]
2605	ADC	analog to digital converter [Section 3]
2606	AEA	Atomic Energy Act [Appendix C]
2607	AL	action level [Section 3]
2608	Am	americium, as an element or one of its isotopes (e.g., ²⁴¹ Am) [Appendix C]
2609	ANSI	American National Standards Institute [Appendix C]
2610	AOAC	Association of Official Analytical Chemists [Appendix C]
2611	APHA	American Public Health Association [Section 6]
2612	APS	analytical protocol specifications [Section 3]
2613	ASL	analytical support laboratory [Section 3]
2614	ASTM	American Society for Testing and Materials [Section 6]
2615	AQCS	Analytical Quality Control Services [Section 4]
2616	ATD	alpha track detector [Section 3]
2617	Ba	barium, as an element [Appendix C]
2618	Be	beryllium, as an element or its isotopes (e.g., ⁷ Be) [Appendix C]
2619	BOA	basic ordering agreement [Section 3]
2620	Bq	becquerel [Section 3]
2621	c	counts [Appendix C]
2622	C	celsius temperature scale [Appendix C]
2623	CC	charcoal canisters [Section 3]
2624	CD	compact disk [Appendix C]
2625	CDF	cumulative distribution function [Appendix C]

2626	CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act [Table 3]
2627	cfm	cubic feet per minute [Appendix C]
2628	CFR	Code of Federal Regulations [Appendix C]
2629	Ci	curie [Appendix C]
2630	Cl	chlorine [Appendix C]
2631	CL	central line (of a control chart) [Section 3]
2632	CLIA	Clinical Lab Improvement Act [Appendix C]
2633	cm	centimeter [Section 4]
2634	COC	chain of custody [Section 3]
2635	COR	contracting officer's representative [Section 3]
2636	cps	counts per second [Appendix C]
2637	Cr	chromium, as an element [Appendix C]
2638	Cs	cesium, as an element or its isotopes (e.g., ¹³⁷ Cs)
2639	d	disintegrations [Appendix C]
2640	DC	direct current [Appendix C]
2641	DCGL	derived concentration guideline level [Section 4]
2642	DFO	Designated Federal Official [Appendix A]
2643	DL	discrimination limit [Section 3]
2644	DoD	U.S. Department of Defense [Section 1]
2645	DOE	U.S. Department of Energy [Section 1]
2646	DOT	U.S. Department of Transportation [Section 3]
2647	dps	disintegrations per second [Appendix C]
2648	DQA	data quality assessment [Table 3]
2649	DQO	data quality objective [Section 3]
2650	EDD	electronic data deliverable [Section 3]
2651	EML	Environmental Measurements Laboratory (DOE) [Section 6]
2652	EPA	U.S. Environmental Protection Agency [Section 1]
2653	Eu	europium, as an element or one of its isotopes (e.g., 155Eu) [Appendix C]
2654	F	fluorine, as an element [Appendix C]
2655	FACA	Federal Advisory Committee Act [Appendix A]
2656	FDA	U.S. Food and Drug Administration [Section 1]
2657	FWHM	full width of a peak at half maximum [Appendix C]
2658	g	gram [Section 4]
2659	Ge	germanium, as an element [Appendix C]

2660	GEDD	general electronic data deliverable [Appendix C]
2661	GM	Geiger-Mueller detector [Appendix C]
2662	GUM	<u>G</u> uide to the Expression of <u>U</u> ncertainty in <u>M</u> easurement (ISO, 1995) [Appendix C]
2663 2664	HASL	Health and Safety Laboratory (renamed the Environmental Measurements Laboratory [EML]) [Appendix C]
2665	Н	hydrogen, as an element or one of its isotopes (e.g., ³ H) [Appendix C]
2666	HPGe	high-purity germanium (semi-conductor) [Appendix C]
2667	I	iodine, as an element or its isotope (e.g., 129I) [Appendix C]
2668	IAEA	International Atomic Energy Agency [Section 4]
2669	IEC	International Electrotechnical Commission [Appendix C]
2670	ISO	International Organization for Standardization [Appendix C]
2671	IUPAC	International Union of Pure and Applied Chemistry [Appendix C]
2672	K	potassium, as an element [Appendix C]
2673	ln	natural logarithm [Section 5]
2674	m	meter [Appendix C]
2675	M	metal ion [Appendix C]
2676	M	molar concentration [Appendix C]
2677	mm	millimeter [Section 4]
2678	MARLAP	Multi-Agency Radiological Laboratory Analytical Protocols (Manual) [Section 1]
2679	MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual [Section 1]
2680	MCA	multichannel analyzer [Appendix C]
2681	MDC	minimum detectable concentration [Section 4]
2682	Mg	magnesium, as an element [Appendix C]
2683	MQC	minimum quantifiable concentration [Appendix C]
2684	MQO	measurement quality objective [Section 3]
2685	MR	moving range [Appendix C]
2686	n	neutron [Appendix C]
2687	NaI(Tl)	Sodium Iodide (Thallium) (semi-conductor) [Appendix C]
2688	NAREL	National Air and Radiation Environmental Laboratory (U.S. EPA)
2689	NBS	National Bureau of Standards (renamed NIST) [Appendix C]
2690	NCRP	National Council on Radiation Protection and Measurements [Appendix C]
2691	nd	nondedect [Section 5]
2692	NELAC	National Environmental Laboratory Accreditation Conference [Section 6]
2693	NIM	Nuclear Instrument Module [Section 3]

2694	NIST	National Institute of Standards and Technology [Section 1]
2695	Np	neptunium, as an element or its isotope (e.g., ²³⁷ Np) [Appendix C]
2696	NRC	U.S. Nuclear Regulatory Commission [Section 1]
2697	0	oxygen, as an element [Appendix C]
2698	ORIA	Office of Radiation and Indoor Air (U.S. EPA) [Section 1]
	OSL	optically stimulated luminescence [Appendix C]
2699		
2700 2701	p	used variously in MARLAP to indicate parameter, percentile, probability [Appendix C]
2702	PDF	probability density function [Appendix C]
2703	pН	negative log of hydrogen ion concentration [Appendix C]
2704	P_1, P_2	photopeaks [Appendix C]
2705	PMT	<u>p</u> hoto <u>m</u> ultiplier <u>t</u> ube [Appendix C]
2706	PTFE	polytetrafluoroethylene (i.e., Teflon) [Appendix C]
2707	Pu	plutonium, as an element or as an isotope (e.g., ²³⁸ Pu, ²³⁹ Pu, ²⁴⁰ Pu) [Appendix C]
2708	QA	quality assurance [Section 3]
2709	QAPP	quality assurance project plan [Table 3]
2710	QC	quality control [Section 3]
2711	Ra	radium, as an element or its isotopes (220Ra, 222Ra, 226Ra, 228Ra) [Section 6]
2712	RAC	Radiation Advisory Committee of the EPA Science Advisory Board [Section 1]
2713	RCRA	Resource Conservation and Recovery Act [Table 3]
2714	Rn	radon, as an element and its isotopes (²²⁰ Rn, ²²² Rn) [Appendix C]
2715	ROI	region of interest [Appendix C]
2716	S	second (time) [Appendix C]
2717	S	sulfur, as an element [Appendix C]
2718	S_1	specific activity of material added to a sample for an isotope dilution analysis
2719		[Appendix C]
2720 2721	S_2	specific activity of material measured in a sample using isotope dilution analysis [Appendix C]
2722	SAB	Science Advisory Board (U.S. EPA) [Section 2]
2723	SCBA	Self-Contained Breathing Apparatus [Section 4]
2724	SI	International System of Units [Appendix C]
2725	SNAP	Systems for Nuclear Auxiliary Power [Appendix C]
2726	SOW	Statement of Work [Section 3]
2727	Sr	strontium, as an element or its isotopes (88Sr, 89Sr, 90Sr) [Appendix C]
2728	Tc	technetium as an element or one of its isotopes (e.g., 99Tc) [Appendix C]

2729	TENORM	Technologically Enhanced Naturally Occurring Radioactive Material [Appendix C]
2730	Th	thorium, as an element or its isotopes (e.g., ²²⁹ Th, ²³⁰ Th, ²³² Th) [Appendix C]
2731	TLD	thermoluminescent detector [Appendix C]
27322733	Type A	method of evaluation of uncertainty by the statistical analysis of a series of observations (ISO, 1995) [Section 5]
27342735	Type B	method of evaluation of uncertainty by means other than the statistical analysis of a series of observations (ISO, 1995), e.g., based on expert judgment [Section 5]
27362737	Type I	decision error that occurs when the null hypothesis is rejected when it is true. The probability of making a Type I decision error is called alpha (α). [Appendix C]
27382739	Type II	decision error that occurs when the null hypothesis is accepted when it is false. The probability of making a Type II decision error is called beta (β) . [Appendix C]
2740 2741	и	standard uncertainty, also known as "one-sigma" uncertainty and expressed as a standard deviation [Appendix C]
2742	U	Uranium, as an element or its isotopes (e.g., ²³³ U, ²³⁴ U, ²³⁵ U, ²³⁶ U, ²³⁸ U) [Appendix C]
2743	UBGR	upper bound of the gray region [Appendix C]
2744 2745	URL	uniform resource locator (protocol for specifying a unique address of a file on a specific computer accessible by other computers) [Appendix A]
2746	US	United States [MARLAP Roster and Executive Summary]
2747	USGS	U.S. Geological Survey [Section 1]
2748	\mathbf{x}_{C}	critical value [Appendix C]
2749	X_{D}	minimum detectable value [Appendix C]
2750		

APPENDIX C 2751 TECHNICAL REVIEW COMMENTS 2752 2753 2754 This master list of comments is intended to be limited to technical comments and some 2755 major editorial comments. Editorial comments are compiled in Appendix D. Comments 2756 compiled in this appendix are not consensus comments. They represent the opinions of individual members of the Review Panel and should not be construed as formal comments of the RAC or the 2757 2758 SAB. 2759 2760 Some of the comments in this appendix have also been included in the main body of this 2761 report. In this case, they can be considered to represent the consensus of the Panel members and formal comments of the RAC and the SAB. The following criteria were used to identify these 2762 2763 comments: 2764 1. Does the comment relate to organization of a chapter or the MARLAP as a whole? 2765 2. Does the comment relate to the credibility of the MARLAP or its usefulness to the user? 2766 3. Does the author of the comment feel strongly that it belongs in the body of the report? 2767 2768 Review comments are listed in order of the chapter to which they pertain. 2769 2770 2771 SEE SEPARATE FILE FOR APPENDICES C AND D 2772